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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

The Honourable Mr. Justice S.G.M. Grange

P.S.A. Lamek, Q.C.

E.A. Cronk

Thomas Millar

Commissioner

Counsel

Associate Counsel

Administrator

Transcript of evidence
for
November 30, 1983

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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
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Hearing held on the 8th Floor,
180 Dundas Street West, Toronto,
Ontario, on Wednesday, the 30th
day of November, 1983.

THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
THOMAS MILLAR - Administrator
MURRAY R. ELLIOT - Registrar

APPEARANCES:

P.S.A. LAMEK, Q.C.)	Commission Counsel
E. CRONK)	
D. HUNT)	Counsel for the Attorney
L. CECCHETTO)	General and Solicitor General
	of Ontario (Crown Attorneys
	and Coroner's Office)
M. THOMSON)	Counsel for The Hospital for
R. BATTY)	Sick Children
D. YOUNG	Counsel for The Metropolitan
	Toronto Police
W.N. ORTVED	Counsel for numerous Doctors
	at The Hospital for Sick
	Children
B. SYMES	Counsel for the Registered
	Nurses' Association of Ontario
	and 35 Registered Nurses at
	The Hospital for Sick Children

(Cont'd)



APPEARANCES: (Continued)

D. BROWN	Counsel for Susan Nelles - Nurse
G.R. STRATHY) E. FORSTER)	Counsel for Phyllis Trayner - Nurse
J.A. OLAH	Counsel for Janet Brownless - R.N.A.
N. GOODMAN	Counsel for Mrs. M. Christie - R.N.A.
S. LABOW	Counsel for Mr. & Mrs. Gosselin, Mr. & Mrs. Gionas, Mr. & Mrs. Inwood, Mr. & Mrs. Turner, Mr. & Mrs. Lutes, and Mr. & Mrs. Murphy (parents of deceased children)
F.J. SHANAHAN	Counsel for Mr. & Mrs. Dominic Lombardo (parents of deceased child Stephanie Lombardo); and Heather Dawson (mother of deceased child Amber Dawson)
W.W. TOBIAS	Counsel for Mr. & Mrs. Hines (parents of deceased child Jordan Hines)
J. SHINEHOFT	Counsel of Lorie Pacsai and Kevin Garnet (parents of deceased child Kevin Pacsai)

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A/BM/ak

1
2 ---Upon commencing at 10:00 a.m.

3 DR. RALPH KAUFFMAN, Resumed

4 THE COMMISSIONER: Yes, Miss Cronk.

5 MS. CRONK: Good morning, sir.

6 DIRECT EXAMINATION BY MS. CRONK: (Continued)

7 Q. Doctor, yesterday you will
8 recall that we discussed, amongst other matters, the
9 likelihood in your view of a medication error having
10 occurred in the cases of Stephanie Lombardo, Jesse
11 Belanger and Jordan Hines and you referred us in the
12 course of your response to those questions to a
13 recent abstract that had been published you said in
14 July of this year having to do with myocardial
15 clearance of digoxin. You have now provided a copy
16 of that abstract to me. I would ask you to identify
17 it as the abstract that you were referring to
18 yesterday.


19 A. Yes, this is the one.

20 Q. As I understand it, Doctor,
21 there are a number of matters that you wish to draw
22 to our attention from that abstract.

23 A. Yes, there are.

24 THE COMMISSIONER: Is this an abstract
25 from textbook.

THE WITNESS: No, I should have



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1
2 identified this at the top before it was copied and
3 I didn't do that. This is an abstract from the
4 proceedings of the International Society for Clinical
5 Pharmacology which met in Washington, D.C. in July of
6 1983 and this paper was presented orally at that
7 meeting and this was an abstract of the paper which
8 was published in the proceedings of that meeting.

9 THE COMMISSIONER: Yes, thank you.

10
11
12 MS. CRONK: Q. Doctor, could you
13 outline for us if you will please the matters that
14 you feel are of relevance?

15 A. Yesterday when I alluded to
16 this paper I was doing so by memory having not looked
17 at it for several months. My memory didn't serve me
18 as well as it should have and, so, I was in error in
19 some of the details that I presented to you and I
20 would like to correct that now and go through the
21 abstract with you and give you the details because I
22 think this is important information in this context.

23 Q. Please do, Doctor.

24 A. This study was carried out on
25



1
2 45 adult patients. I don't remember specifically
3 yesterday whether I said they were adults or children
4 but these were on 45 adult patients who were under-
5 going open heart surgery and had been on chronic
6 digoxin therapy for at least six months or longer at
7 the time of their surgery. So, they were on chronic
8 digoxin therapy.

9 At the time of surgery serum digoxin
10 was measured in their serum as well as in samples
11 taken from atrial myocardium or papillary muscle
12 ventricular myocardium and the time at which the
13 digoxin sample was taken varied with each patient of
14 after their last dose; in other words, the time from
15 the last dose of digoxin to the time of the sampling
16 varied with each patient from anywhere from one day
up to 20 days.

17 Getting these samples then and pulling
18 this data the authors attempted to estimate the half
19 life with which digoxin in this particular group of
20 patients disappeared from the serum and from the
21 heart. This is the first information that I am aware
22 of where this specific issue has been addressed
experimentally in human beings.

23 The decline in serum digoxin levels
24 had a beta half life in this particular group of
25



1
2 patients of 48 hours. There is a variation but this
3 was the average. The decline in the heart muscle
4 levels were essentially the same, the half life was
5 essentially the same for both atrial and ventricular
6 myocardium but it was longer than the serum.

7 The decline in myocardium during the
8 alpha phase or what appeared to be an alpha phase,
9 the short half life phase, was 7 to 12 hours and the
10 slow elimination or the so-called beta phase was
11 three and a half days for papillary muscle and four
12 and a half days for right atrial appendage but this
13 was not statistically significant.

14 In some of the patients, and I don't
15 know how many, but in some of the patients who had
16 received their last digoxin dose 20 days prior to
17 surgery digoxin was still present and detectable in
18 the tissues up to 20 days.

19 Q. Thank you, Doctor. May I, in
20 light of the information afforded by this abstract,
21 Doctor, take you now back for a moment to the case
22 first of Stephanie Lombardo. You will recall in that
23 case that the child was admitted to the Hospital on
24 December 13th and died December 23rd and that there
25 were assay results both on RIA, HPLC and RIA and on
mass spectrometry from the Centre of Forensic Sciences



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2 showing digoxin in a variety of tissues in that child.

3 Given the information provided by this
4 abstract, would you expect to see first traces of
5 digoxin in tissue samples from that child if a
6 therapeutic or maintenance dose of digoxin was given
7 to the child at any point during those 10 days?

8 A. There are two caveats that
9 we have to look at; one is that the study that I just
10 alluded to was done in middle age adults. So, I
11 don't know whether they would be different than
12 infants; the second is that they were on chronic
13 digoxin therapy. In this case we are postulating a
14 single dose of a maintenance dose by error. We know
15 that the concentrations in the tissues are much higher
16 with chronic therapy than with the single dose and
17 the total amount of digoxin in the patients in the
18 study would be considerably greater per body weight
19 than the amount of digoxin in the total body after a
20 single maintenance dose. So, we have to take that
21 into consideration.

22 But accepting that, I think if we are
23 willing to extrapolate the data from this study to
24 the situation of Lombardo, I think I would say it
25 would be possible following a single dose some time
during that 10 days to still be able to detect



1
2 digoxin in myocardial tissue within that 10 day
3 period. It is hard for me to assign a probability
4 value to it but I certainly think it would be possible.

5 Q. And that I take it, Doctor,
6 would equally be the case, if not more so, were it
7 a loading dose that were given to the child in error
8 as opposed to a maintenance dose.

9 A. Well, half of the usual loading
10 dose, which would be the situation with a single
11 error, would be approximately twice a maintenance
12 dose received error. So, he would expect to be able
13 to detect the digoxin in tissues a little bit longer
14 simply because there was more digoxin there to begin
with.

15 Q. I understand. Doctor, having
16 regard to the specific levels of concentrations of
17 digoxin which were found in Stephanie Lombardo, you
18 will recall that you told us yesterday that in your
19 view, as I understood it, they were both high and,
20 secondly, that they were consistent in that they were
21 in a variety of different tissue specimens from her
22 body. The levels in the heart you will recall were
23 within the range of 487 in the left ventricle to
24 667 in the septum of the heart and in chest fluid
25 it was 225 nanograms.



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3 Given the actual concentrations that
4 were found in the child and the number of tissues in
5 which concentrations of digoxin were found, would you
6 consider it likely in your view that those concentra-
7 tions would be found in this child if a therapeutic
8 or loading dose were given at any time within the 10
9 days prior to her death?

10 A. We have to consider the
11 problem of interpreting numbers from exhumed tissue
12 but if we would accept those numbers of being somewhere
13 in the ball park of what the concentration was at the
14 time of death, then I think it would be quite unlikely
15 that it would be due to medication error 5 to 10 days
16 earlier. The problem is the interpretation of the
17 exhumed tissue concentrations.

18 Q. Does the abstract, Doctor,
19 that you provided to us give any indication as to the
20 actual concentrations that were found in the myocardial
21 tissues, be it the one or the 20 days that were
22 sampled. Do we know how much was found?

23 A. Well, the average concentration
24 that they mentioned according to my notes from the
25 paper, from hearing it, their actual concentration -
these are averages - the average concentration went
from around 300 nanograms per gram down to approximately



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2 3.5 nanograms per gram over 20 days. So that although
3 they could detect it by 20 days the concentrations
4 were very, very low.

5 Q. All right.

6 THE COMMISSIONER: Am I to read this
7 that 20 days is the last or is it the last day tested?
8 Do they test for 21 or 22, do we know?

9 THE WITNESS: No, that's the longest
10 interval between the last dose and surgery.

11 THE COMMISSIONER: That is not quite
12 what they say, unfortunately. "Measureable levels of
13 digoxin were still present on both tissues 20 days
14 after stopping treatment." They don't say that they
15 were not detectable 21 days after. But I take it
16 that is what they mean, is it?

17 THE WITNESS: But the method of
18 the study was that the longest time they measured it
19 was 20 days. They don't know if it was there longer
20 because they didn't measure it.

21 THE COMMISSIONER: That's right.

22 THE WITNESS: They didn't have any
23 patients who had not received a dose for more than
24 20 days before they had their surgery.

25 THE COMMISSIONER: But measureable
levels of digoxin, they don't say how low they were.



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THE WITNESS: Well, from my notes from hearing it - you see, many details aren't in the abstract.

THE COMMISSIONER: Yes.

THE WITNESS: From my notes that I took when I heard the paper presented I have a note that the average concentration declined from 300 nanograms per gram to an average of 3.5 nanograms per gram over these 20 days.



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You have to remember that each patient represented one sample, and so they pooled the data from the 45 patients and there are some theoretical problems with that but it is really the only way you can address this problem in patients.

Q. They found then, doctor, after 20 days I take it on average a concentration that would be considered to be of the upper range of the therapeutic level were it achieved during life, for example?

A. I am sorry?

THE COMMISSIONER: And if it were in serum.

MS. CRONK: Q. And if it were in serum, 3.5, the highest was 3.5 that they found after 20 days?

A. The average.

Q. The average, right.

A. I don't know the range, that wasn't provided.

Q. Thank you, doctor.

Doctor, could we turn then similarly to the case of Jesse Belanger for a moment. You will recall that this child from the time of his admission to the Hospital to the time of his death was hospitalized for approximately 35 days. Again given the information



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that is available to you from the abstract, and having regard to the concentrations that were found in this child, is it possible in your view that traces of digoxin could be found in tissues, and remember again that they are exhumed tissues, from his body if a therapeutic or loading dose of digoxin had been administered to him in error at any time during that 25-day period?

A. I suppose it is possible, but considering the dose that he would have received under those conditions I think it is highly unlikely that it would be detected as long as 35 days.

Q. Doctor, just to refresh your memory on that as well, you will recall that with Jesse Belanger the actual concentrations found, one was assayed again both by RIA, HPLC/RIA and as well mass spectrometry, and in the liver by those methods a concentration of 253 nanograms per gram was found; and in a sample of skeletal muscle a level of 43 nanograms per gram was found.

Having regard to the actual concentrations, is it your view that it is likely that those levels could be found if one therapeutic or loading dose had been administered at any time during the 35 days?



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A. Again with the problem of interpreting the concentrations because of the nature of the sample; if we accept those numbers as being somewhere in that general range, then I think it is even more unlikely that those kinds of levels would have been detected for a prolonged time after a dosing error.

Q. Doctor, I take it as well though as Dr. MacLeod suggested in his evidence, based on this abstract it is certainly possible that some tracings of digoxin might be found in tissues?

A. Yes, I think that is possible considering -- well, if you have a sensitive enough assay and if the initial concentrations were high enough to leave a trace that long afterwards, a detectable trace. I have to say, yes, I think it is possible, looking at the entire picture here I think it is somewhat improbable but I think it is possible.

Q. Doctor, then may we turn to the case of Jordan Hines. There is a shorter time interval still in his case. You will recall that it is approximately, I believe I have this correctly, two days between the time of his admission for something under 48 hours and the time of his death. Again in his case we are dealing both with fixed and exhumed



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specimens. The levels in the fixed heart tissue range between 52 nanograms per gram in the left ventricle, and 89 nanograms per gram in the septum; digoxin was as well found in exhumed tissues from the right thigh muscle 56 nanograms per gram. Assuming, doctor, that one therapeutic or one loading dose of digoxin was in error administered to that child during the two-day period of his hospitalization, at any point over the two days, would you consider it possible to find those concentrations of digoxin in his tissue specimens after death?

A. Yes, I think it would be possible.

Q. And are you, doctor, able to express in this case any opinion as to the likelihood of concentrations of that kind being found, if for example, a therapeutic or loading dose was given shortly after his admission to the Hospital?

A. Well again if you can accept the fixed tissues as being the minimum that it could have been, and you estimate what concentration might be produced, what maximum concentration might be produced under those conditions, I think it is possible, and I think it is difficult to assign a probability to that. I think that it is somewhat unlikely that it



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would have been given as long as 48 hours, but I think that it is -- the probability of it being given that long and not being given that long I would say is essentially equal based on this kind of information that I have just presented to you.

Q. And given as well I take it, doctor, the actual length of time involved, that is two days?

A. Yes.

Q. Thank you, doctor.

Mr. Commissioner, before I continue, Mr. Brown indicated to me this morning that he wished to address some remarks to you.

THE COMMISSIONER: Yes, Mr. Brown.

MR. BROWN: Mr. Commissioner, on occasions before you have suggested to me perhaps this is not the proper place to address matters which arise in the media.

Yesterday, however, the expurgated version of the Atlanta Report was released and was made an exhibit in this Inquiry. Numerous reports appeared in the press regarding that report, and in particular a report appeared on Global Television and there was a picture of a portion of a page of the report of which part of the report had been blacked out. I did not



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personally see the television program on Global,
although I was informed of its contents, and I believe
a comment was made on that portion of the report that
was blacked out. The comment was made suggesting that
the blacked-out portion referred to Nurse Susan Nelles.

I have reviewed the expurgated
version of the Atlanta Report and I have reviewed the
unexpurgated version of the Atlanta Report and from
my review --

THE COMMISSIONER: Wait.

MR. BROWN: I will be careful.

THE COMMISSIONER: Yes. All right.

MR. BROWN: From my review I have
been able to ascertain that those portions of the
Atlanta Report which were blacked out did not refer
directly or indirectly to Nurse Susan Nelles.

It is difficult in a Commission of
this nature to put in evidence piecemeal, although I
think there was agreement previously that the Atlanta
Report would be put in only at the proper time.

However, in view of the difficulty
in interpreting any information which may be blacked
out, I take great offence to the suggestion that was
made on Global Television; I take offence to any
speculation which is made by members of the media; and



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I further take offence to speculation which is wrong.

THE COMMISSIONER: Yes. Well they couldn't conceivably have known what was in the blacked-out portion unless they obtained a copy of the unexpurgated report, so they could not have known at all and so therefore it had to be speculation.

MR. BROWN: The blacked-out copy, Mr. Commissioner, is readily subject to analysis and one can readily determine what has been blacked out. That has happened on previous occasions when particular Minutes of meetings were put in. I think the Minutes of the September 13th meeting, and I believe that happened again on this occasion.

THE COMMISSIONER: I had no idea you could do this sort of thing, can you?

MR. BROWN: I believe the media are quite adept and I concede that may well be their job to try and glean any bit of information they possibly can.

THE COMMISSIONER: Well what do you propose, what remedy are you proposing, or are you merely announcing your discontent?

MR. BROWN: Well I am merely announcing my grave discontent over this matter.

THE COMMISSIONER: Yes.



B8

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2 MR. BROWN: And perhaps as a remedy
3 there is a practical solution. In future if documents
4 are going to go in, and part of documents are going
5 to be expurgated, the safer procedure perhaps to
6 avoid incorrect speculation would be simply to white
7 out or physically excise those portions of the document.
8 It would make it that much more difficult for the
9 media and would prevent speculation which is completely
10 incorrect and unfounded.

11 MS. CRONK: Well, Mr. Commissioner,
12 I cannot comment on what was or was not said or
13 implied directly or indirectly last evening because I
14 did not see the program, nor until just this moment was
15 I informed about it.

16 I can say on behalf of both Commission
17 Counsel, Mr. Lamak and myself, that if it was possible
18 by process of deduction or clairvoyance to understand
19 what was beneath the blacked-out parts of the report
20 and if this has caused difficulty for Mr. Brown we
21 regret that. I don't think I need to go into the
22 difficulties of doing that, but I can assure Mr. Brown
23 that I certainly couldn't and we have undertaken
24 whatever efforts we could.

25 THE COMMISSIONER: Can it be cut out?

MS. CRONK: We certainly can, and



1
B9 2 indeed if the situation arises in the future we will
3 be glad as we did yesterday to consult with Mr. Brown
4 in advance as to the most appropriate method to achieve
5 that.

6 THE COMMISSIONER: Mr. Young had
7 better worry about this, because if the media teaches
8 the trick to some of the other counsel that police
9 report is being done the same way so you may be in
10 trouble.
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Well, I agree. It could only have been speculation. For what it is worth I would just as soon people didn't speculate. We have a very good reason for not releasing the whole of the Atlanta Report. We are not going to do it until we have to, and when there is an opportunity to reply to it, and that opportunity will not apparently be available until at least January.

So like you I regret that that has happened, but I don't know that there is anything more I can do than regret it. I don't want them to say any more. What they have said now --

MR. BROWN: Oh, I appreciate that and my remarks --

THE COMMISSIONER: -- has caused some trouble and --

MR. BROWN: My remarks of course were not directed to Commission counsel. I was simply voicing a concern over incorrect speculation, how that can occur, and I think perhaps a practical remedy is to avoid --

THE COMMISSIONER: Practical remedy is to prevent it from happening again.

We have now released not the Police report but we have released the minutes, have we not, in this matter?



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MS. CRONK: Yes we have, sir.

THE COMMISSIONER: And blackened things out?

MS. CRONK: Well, actually in that case I think Mr. Lamek may have demonstrated another talent and taken scissors to them.

THE COMMISSIONER: Yes.

MS. CRONK: But I am not sure of that so I will check.

MR. YOUNG: Just to be clear, in the September 13th notes of the meeting involving the police --

THE COMMISSIONER: They were blacked out.

MR. YOUNG: I think they were blacked out in the latter case. Miss Cronk is absolutely correct.

Mr. Lamek's cut and paste, he did an excellent job.

THE COMMISSIONER: Well I guess we have learned something now and that is what we will do in future.

All right. Thank you. Miss Cronk?

MS. CRONK: Q Dr. Kauffman, yesterday at the end of the day we were discussing the case of Kevin Pacsai and as you may recall you had outlined



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for us first what your conclusion was in this case,
and secondly the basis for it.

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You will recall, Doctor, in this case
as well that in addition to both the ante mortem and
post mortem serum digoxin levels which were available
and to which you referred there are available digoxin
readings in fixed tissues.

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In the report prepared by the Centre
for Forensic Sciences dated January 11th, 1982, a
concentration of digoxin in the amount of - ranging
in the amounts of 102 to 105 nanograms per gram were
recorded for the heart; that is fixed tissue, and as
well a pure digoxin reading of 48 nanograms per gram
was recorded in fixed lung tissue.

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I take it, Doctor, obviously you had
those concentrations and that data available to you
at the time you were assessing the case?

17

A. Yes, I did.

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Q. In addition, however, Dr.
Kauffman, in a report dated September 29, 1982 from
the Centre for Forensic Science (that is Exhibit 95E,
sir) Mr. Cimbura reported a digoxin concentration of
122 nanograms per gram in frozen lung tissue.

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As I heard your evidence yesterday you
did not refer to that concentration or that specimen.



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Were you aware of that level at the
time that you were assessing this case originally?

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A. No, I was not aware of that when
I drafted the first report.

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Q. Right. And, Doctor, were you
subsequently informed with respect to that data?

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A. Yes, I was subsequent to
submitting a report.

9

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Q. All right. And were the
implications of that level then considered by you prior
to the delivery of your second reporting letter to
Mr. Wiley?

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A. Yes, it was.

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Q. And once you learned of the
reading and reassessed this case in light of that
reason, Doctor, can you help us to what your conclusion
then was?

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A. I don't think it changed my
original conclusion substantively. It supported it
and tended to increase the probability of my conclusion
being correct, but I saw it as supporting data, hence
supporting the initial impression I had gained from
the other information.

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Q. And, Doctor, if we turn to page
3 of your second reporting letter to Mr. Wiley in the



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first full paragraph set out on that page dealing with Kevin Pacsai, you indicate with respect to the lung tissue concentration:

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"Therefore, the concentration in the fresh autopsy lung is not definitive but supports the theory that this patient received a toxic dose of digoxin prior to death. The digoxin measurement in lungs does not change my original evaluation of the Pacsai case other than to strengthen it."

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Which of course is just what you suggested to us, Doctor.

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The language of the second reporting letter, however, indicates that in the absence of knowledge of the fresh lung tissue specimen you had already concluded that it was probable that digoxin intoxication had contributed to this child's death. Is that correct?

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A. That is correct.

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Q. May we turn then, Doctor, to the basis upon which you reached your initial conclusions.

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You told us clearly that you were aware of the ante mortem blood sample with the level of greater than 10 nanograms. Is that correct?



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Q. You told us as well that you were aware of the post mortem serum levels which ranged from 24 to 26 nanograms, the mid point being 25.5 nanograms as tested both at The Hospital for Sick Children and at the Centre For Forensic Sciences.

Were you also aware, Doctor, that the same post mortem specimen which resulted in a reading at The Hospital for Sick Children of 26 nanograms had been assayed for digoxin at Mount Sinai Hospital?

A. I was aware of that, yes.

Q. Were you then aware, Doctor, that a level of 112 nanograms was reported after several dilutions at Mount Sinai Hospital on that specimen?

A. Yes, I was aware of that.

Q. What significance, Doctor, if any, did you attach to the reading from Mount Sinai Hospital?

A. It was so out of line with the assays performed at The Hospital for Sick Children and the Centre for Forensic Studies that I viewed it as outlier, an error if you will, and discarded it essentially from my consideration in making my conclusions.

Q. It played then I take it no



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part in the formulation of your opinion?

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A. I think that is correct, yes.

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Q. And, Doctor, what significance did you then attach to the ante mortem level of greater than 10 and the post mortem levels on serum that had been recorded at The Hospital for Sick Children and the Centre for Forensic Sciences?

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A. The ante mortem level of 10 I had no way of knowing if that was 10 or something up to as much as 25 which reflected the post mortem concentration. So I had to assume that the real concentration ante mortem was somewhere in that range.

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I could not really go further than that. When I estimated possible doses which could have accounted for this, I picked a middle concentration in the mid part of that range, but I had no way of knowing specifically where within that range the real number may have been.

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Q. Well, we will come back to this, Doctor, but as I understand it when you came to actually to attempt the amount of dose that might have been given to the child you chose a mid point for the ante mortem serum concentration of 15 nanograms?

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Do I have that correctly?

A. That is correct.



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Q Doctor, in your view was the post mortem serum level of 26 nanograms consistent with the ante mortem serum level of greater than 10?

A. Yes, I thought it was.

Q Doctor, we have heard as you know evidence from a number of biochemists from The Hospital for Sick Children. One of those, Dr. Ellis, has told us in evidence that at the time that the ante mortem specimen was being tested two dilutions were run and there was then from that point forward insufficient sample for further dilution.

He has said as well that there is a number recorded in the laboratory digoxin books beside the actual level. The number recorded is 10.6.

He has told us in evidence that that may be representative of the number extrapolated by the computer when the computer plotted out the graph although there was no further possibility of further dilution.

He has suggested therefore, in evidence, Dr. Kauffman, that the actual computer extrapolated number could have been first 5.3, which on a dilution of 2 would make the actual reading on the ante mortem sample of 10.6; or, alternatively, the actual computer extrapolated number could have been 10.6



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which on a dilution of 2 would make the actual ante mortem reading approximately 21 to 22 nanograms.

Do you understand the evidence so far as I put it to you?

A. I think so.

Q. All right.

Doctor, if in fact the ante mortem reading was 10.6 nanograms after all dilutions were complete, and the post mortem levels we know were between 24 and 26 nanograms, I take it we can agree that would reflect a multiplier effect or a post mortem elevation of something less than 3?

A. If I knew for certain that the ante mortem level was 10.6 and then was presented with post mortem concentrations in the serum of 25, I could very well accept that. I have no problem with that. That is well within the range of changes that are reported post mortem.

Q. And that I take it would be the case when we are considering the multiplier effect if the ante mortem level was in fact 21 or 22?

A. That is correct because as you know the multiplier and, the so-called multiplier - I don't like that term but I will use it - can be anywhere from no change to up to fourfold.



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Q. All right. Doctor, if the ante mortem reading was in fact 21 or 22 nanograms, apart from the multiplier effect, would that level in your view be consistent with the post mortem readings on serum that were actually achieved?

A. Yes. I have no problem with either of those numbers in terms of reconciling them with the post mortem concentrations.

Q. Doctor, may we turn then to the ante mortem potassium levels that were recorded for Kevin Pacsai. You alluded to those yesterday in explaining the basis for your assessment of this case and we know from the medical record of the child, Doctor, that on March 11th his serum potassium level was 3.9; on March 12th it was 9.0, but the evidence suggests that that was a hemolyzed sample; and on March 12th, later still in the day the level was 7.7.

If the potassium level of those numbers be accurate then, Doctor, it went from 3.9 to 7.7 in something slightly over 12-13 hours. What significance if any, Doctor, did you attach to those levels when you were assessing this case?

A. At the time I was assessing the case, and I think I still agree with this with myself, I viewed that as being, the 7.7 as being a real change



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2 from the 3.9. It concerned me that it had changed
3 for a 12 to a 13 hour period. I looked to see if there
4 was any evidence that the child had decreased kidney
5 function because that could have helped explain it.
6 I couldn't explain it that way because his blood
7 urea nitrogen is reported to be normal on two
8 occasions, including the time of that high potassium
9 level.

10 I looked to see if he had any degree
11 of acidosis or hypoxia which could explain the high
12 potassium level and, again, a blood sample obtained,
13 it looks like approximately two hours prior to the
14 second potassium sample. His blood gases were normal,
15 his pH was 7.7, his oxygen was 161, which is quite
16 high but I think he was getting some additional
17 oxygen.

18 So, he had neither hypoxia nor
19 acidosis documented around this time and I couldn't
20 account for the high potassium based on those criteria.

21 So, putting it together with his
22 clinical symptomatology, with the elevated digoxin
23 concentration which was also drawn around the same
24 time, I had to conclude that the most probable explanation
25 was that the potassium elevation was a part of
the digoxin intoxication.



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Q. Could renal failure, Doctor, or a form of renal failure account for an elevated serum potassium level of the kind seen in this child?

A. It can if it is severe enough and for a prolonged period of time, yes.

Q. And if the child were experiencing any degree of renal impairment or renal failure, would you expect to see changes in the blood gases of the child?

A. Not necessarily the blood gases; you might. Children with certain kinds of renal failure can have some degree of acidosis but not necessarily, depending on what kind of renal failure you are talking about. But I would have expected to see some degree of evidence of renal failure if it was responsible for the high potassium. I don't know if I have answered you or confused you.

Q. No, I think you have, Doctor. I take it then that one possible explanation then for high serum potassium, apart from renal failure, is then acidosis or hypoxia?

A. Yes, high potassium can be a result of severe acidosis. As I said yesterday, with acidosis there is an increased concentration of hydrogen ions, they tend to exchange in the cell and



1
2 are exchanged for potassium which comes out of the
3 cell and that makes the serum concentration of potas-
4 sium go up.

5 Q. All right. And it was for that
6 reason then that you addressed specifically the blood
7 gas levels of this child over the two days of his
hospitalization?

8 A. Yes, that is correct.

9 Q. All right. Doctor, what about
10 the BUNs of this child, did you review those as well?

11 A. Yes, I did.

12 Q. All right. Could I ask you
13 to turn to page 81 of the medical record first.

14 A. I don't have a copy of the
15 medical record with me.

16 Q. All right.

17 I'm sorry, Mr. Registrar, that is
18 Exhibit 106. Oh, it's here. k

19 A. Oh, it's here. Which page, 81?

20 Q. 81, Doctor. This child was
21 admitted to The Hospital for Sick Children on March 11th,
22 Doctor.

23 A. Yes, I see.

24 Q. All right. And on page 81 we
25 see do we not one BUN reading for March 11th and one



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again for March 12th, both less than 5.

A. Yes, that's correct.

Q. What significance do these levels have for you, Doctor?

A. I think they are normal for an infant this age.

Q. Doctor, in assessing the blood gas history of the child, if you will, during life and as well the possibility of renal failure, did you take into account what the levels had been at McMaster Hospital prior to referral to The Hospital for Sick Children?

A. Yes, I had.

Q. And what was your view of the levels recorded at the referring hospital some days prior to admission to The Hospital for Sick Children?

A. Are you talking specifically about blood gases or BUN or...?

Q. Let's deal with blood gases first, Doctor.

A. All right. I was aware that upon his admission to McMaster he had been severely acidotic, as I recall a pH in the neighbourhood of 6.9. As I recall from the summary of his course there and his medical record this degree of acidosis was



1
2 slowly corrected over the next several hours and he
3 was eventually returned to a normal pH before his
4 transfer from McMaster. That was approximately three
5 days prior to his admission to Sick Children's I
6 believe, correct me if I'm wrong.

7 Q. That is my understanding,
8 Doctor, that the levels were reported on March 8th.

9 A. Right. So, I took this into
10 consideration but I thought that an acidosis, an acute
11 acidosis which was corrected over several hours three
12 days prior and the child had documented normal blood
13 gases subsequent to that, at least when they were
14 measured, that I couldn't account for any high
15 potassium on the 12th March due to an acidosis four
16 days earlier.

17 Q. And did you, Doctor, with
18 respect to the --

19 A. Pardon me, especially since he
20 had had a normal potassium documented 12 hours prior
21 to that high potassium.

22 Q. On March 11th?

23 A. Right.

24 Q. Doctor, did you, in addressing
25 the BUN levels taken at McMaster Hospital, have any
concerns at that stage that he might have been



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evidencing some degree of renal failure?

A. Excuse me, I will have to refer to the BUN levels from McMaster, I don't recall those specifically. I should look at them before I answer you. Can you refer me to the page or information on the BUN?

Q. The blood gases, Doctor, are set out at page 38 of the record and at pages -- I am not sure if page 42 would help you, Doctor.

A. My copy of page 42 is illegible.

Q. I am showing you my copy of page 42, Doctor, and on the right-hand side of the page towards the bottom recorded I believe for March 8th, 1981, are the BUN levels taken at McMaster Hospital.

A. Yes, that is correct. The BUN was recorded as 31 and the creatinine, which is another measurement of kidney function, was 1.3. The creatinine concentration is elevated for a baby this age, as is the BUN, which indicates that the child was experiencing, at least temporarily, some degree of decreased renal function at that point in time. This isn't surprising since his cardiac output was dramatically reduced at that time due to his arrhythmia and it is consistent with the acidosis that was observed



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2 at the same time. Apparently his kidney function
3 corrected then after his heart problem was corrected
4 at the same time.

5 Q. And we see, Doctor, that in the
6 period between -- and to help you, I stand to be
7 corrected, but I don't think there are any other BUN
8 levels recorded for March 9th and March 10th, but
9 certainly on March 11th we have seen that the level
10 was down to less than 5.

11 A. That is correct.

12 Q. All right. I'm sorry, that is
13 the only level we have seen and it was repeated on
14 March 12th and again it was less than 5.

15 A. Yes.

16 Q. All right. Doctor, as I under-
17 stand it in this case you did as well attempt to
18 estimate both the amount of a minimum dose of digoxin
19 which could account for the serum and tissue levels
20 in this child and as well to estimate the likely amount
21 of administration of the digoxin. Do I have that
22 correctly?

23 A. Yes, that is correct.

24 Q. May we deal first, Doctor,
25 with your conclusions regarding the likely method of
administration of the drug.



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2 A. I couldn't be certain on this
3 child whether it might have been given by injection or
4 orally. I think the possibility is equal either way.
5 I felt from his course as described in the chart that
6 it was unlikely that he received a large bolus close
7 to the time of his death and that impression was
8 affirmed by the fresh lung tissue specimen, which
9 indicated to me that there had indeed been significant
10 distribution to the tissues prior to his death.

11 So, I really couldn't make a
12 distinction between whether or not he might have
13 received a dose parenterally or orally.

14 Q. Are the digoxin concentrations
15 found both in the fixed and frozen tissues of this
16 child, Doctor, consistent in your view with a dose
17 administered several hours prior to the onset of his
18 critical symptoms?

19 A. I think it is consistent with
20 several hours prior to or even a little bit longer.

21 Q. Well, you have told us, Doctor,
22 that it was your opinion having regard to what you
23 perceived to be the distribution of digoxin to tissues
24 that a large bolus administered intravenously was
25 unlikely. Were you able to put a time frame based on
the information available to you on the most likely



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time of administration of the drug?

A. I really couldn't pin it down very well. When I looked at it, I had the impression from looking at the description of the events over approximately a 12-hour period prior to his arrest that there was something happening as early as 3:30, 3:45 that morning when the nurse described him as being very different from what he had been before and being limp and so forth. It appeared to me that that could possibly be the beginning of intoxication symptoms which then progressed over the subsequent hours to varying degrees of dysrhythmia, ultimately culminating in an arrest from which he could not be resuscitated.

If I accepted that relatively slow progression of events rather than the sudden catastrophic description which existed in some of the other cases, then it made most sense to me that he might have received a dose orally some six to twelve hours prior to the onset of this dramatic change in his condition. But I couldn't pin it down with any confidence more tightly than that.

Q. Doctor, what are you regarding as the onset of this change in his clinical condition that you have described?



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A. In that scenario I was regarding the change in his condition described at approximately 3:45 to four o'clock the morning of the 12th of March.

Q. Could I ask you, Doctor, to take a look at the progress notes of this child commencing at page 65. Do you have that, Doctor?

A. Yes, I have page 65.

Q. You will see there in the middle of the page a nursing note for the period 3:45 in the morning to six o'clock and as well back on page 63 a note by Dr. Costigan as to events at 5:30 in the morning. Do either of those notes help you in terms of what you were regarding as the significant alteration in condition which you have described?



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A. I was referring specifically - well, I took all of this into consideration, but I was referring specifically to the note in the middle of the page on page 65:

"0345-0600 March 12/81".

Where a comment is made:

"...attempted to feed babe and his behaviour was entirely different from the other two times. He was lethargic and limp in my arms."

His apical rate - "...very irregular, monitor was showing bouts of tachycardia alternating with periods of bradycardia and rhythm strip showed occasional 2 to 1 block."

Then more descriptions subsequent to that. From the chart there seemed to be a distinct change from what had occurred from his condition earlier following his admission.

Q. I suppose the difficulty that we have, Doctor, is that the nursing note on that page covers a matter of several hours in describing those symptoms, and it is not I suggest clear from that note as to when those symptoms actually took place, when those manifestations actually took place?

A. That is correct.



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Q. But we know from page 63 do

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we not, that when Dr. Costigan made his note recorded
4 to be at 5:30, that he was recording having seen the
5 child because of anxiety and the bradycardia, and he
6 then described the drop in blood pressure and the
7 varying arrhythmias recorded on the rhythm strip?

7

A. Right.

8

Q. That is at 5:30 at night?

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A. Right. So there is some

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ambiguity as to the exact time that these symptoms
11 evolve, and I suspect that they evolved over a period
12 of time from the time they were first noticed until
13 they are described, or have been described by several
14 observers.

14

Q. Doctor, could I refer you please
15 as well to page 8 of your first report to Mr. Wiley.

16

In the portion of the report dealing with Kevin Pacsai,
17 in the third full paragraph, the issues of the likely
18 dose and the likely time of administration are
19 addressed. You indicate midway through that para-
20 graph that in your view:

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"...the development of hyperkalemia
21 over a 12-hour period in the absence
22 of severe renal failure suggests
23 digoxin was given some hours before
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2 "the onset of critical symptoms".

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4 Do I correctly have it, Doctor,
5 then, that quite apart from the concentration of
6 digoxin found in the fresh lung tissues, that you
7 thought that the development of the hyperkalemia
8 as well suggested a more progressive development of
9 digoxin toxicity?

10 A. Yes, that is correct.

11 Q. And, Doctor, you have suggested
12 as I read it in the next sentence, that this child
13 could have received an excessive dose of digoxin
14 orally at the time that he received his last prescribed
15 dose, that is 11 o'clock, 11:00 p.m. on the evening
16 of March 11th, do I have that correctly?

17 A. Yes. It occurred to me that
18 in looking, trying to look at all the possibilities
19 that one alternative was that he could have received
20 an excessive dose at a usual dosing time rather than
21 a non-scheduled dose being administered, since I felt
22 that the highest probability was that he had received
23 it some time, some hours prior to development of his
24 symptoms.

25 Q. And you suggested as well,
Doctor, as I read your report, that he could have
received an excessive dose at both prescribed dosing



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2 times on March the 11th, in this case that would make
3 it at 9:00 a.m. and 11:00 p.m. when the doses appear
4 to have been administered to the child, is that your
5 view?

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6 A. I thought that was another
7 possibility, yes.

8 Q. The medication record for
9 Kevin Pacsai, Doctor, indicates that on March 11th -
10 perhaps I would ask you to turn to this, this is at
11 page 80 of the medical record. Do you have that,
12 Doctor, page 80?

13 A. Just a moment. Okay.

14 Q. The medication and treatment
15 record indicates that at 11:00 p.m. on March 11th
16 the child received .02, is that milligrams, Doctor,
17 orally?

18 A. I assume that is milligrams,
19 I see mgm, then po BID, so I assume that is milligrams.

20 Q. And appears as well to
21 have received a like amount at 9:00 a.m. that morning?

22 A. That is correct.

23 Q. Doctor, dealing only for the
24 moment with the dose at 11 o'clock on March the 11th,
25 is that amount, the amount recorded ---

THE COMMISSIONER: I am sorry, is



1
2 this possible?

3 MS. CRONK: I am sorry, sir.

4 THE COMMISSIONER: I don't understand
5 this. They are all dated the 11th of March but the
6 9:00 a.m. one is that - I am sorry.

7 MS. CRONK: My understanding Mr.
8 Commissioner, was that at 9:00 a.m. on March the
9 11th the child received a maintenance dose in that
10 recorded amount and then he received a second at
11 11 that evening.

12 THE COMMISSIONER: Yes, that is all -
13 yes, all right.

14 MS. CRONK: That pertains of course
15 only to the digoxin. He received a number of other
16 medications as noted.

17 THE COMMISSIONER: That was 11 that
18 evening?

19 MS. CRONK: 2100 hours.

20 THE WITNESS: I am confused.

21 MS. CRONK: I am sorry, 9, I am saying
22 11, it is 9. You are quite right, sir, the
23 mathematical error, the timing error is mine.

24 THE WITNESS: I am confused, I am
25 not sure what actually happened here. Because on
medication sheets like this, when the order is written



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2 off, at least in our Hospital, the way the drug is
3 to be given is written on the medication sheet just
4 as it is here and the times that it is to be given
5 in the future is written, and then it is initialled
6 only at the times that it is actually given. It
7 appears to me from this note that the first dose,
8 the word "start" is there and the nurse's initials
9 underneath it, the first dose was administered at
2100 on the 11th.

10 Q. And that it is possible ---

11 A. No dose was given at 900 on the
12 11th, that was simply the time from the order that
13 it would be given subsequently.

14 Q. I see. Well, dealing then,
15 Doctor, just with the dose which you feel most likely
16 to have been given, at least as recorded, the one
17 at 9:00 p.m. that evening; if the amount that is
18 recorded in the medication treatment record was in
19 fact the amount that was given, that is if .02
20 milligrams was given to the child, could that
21 account for the ensuing clinical course and serum
digoxin levels found in this child?

22 A. No, I don't think so.

23 Q. Doctor, if at that time -
24 well leaving aside then for the moment the issue of
25



1
2 an excessive dose; as I understand it you did attempt
3 to calculate what in your view was the very minimum
4 dose that the child could have received to achieve
5 those levels?

6 MR. OLAH: Perhaps my friend
7 before she proceeds, would like to put the
8 time that the potassium sample was taken at 1745
9 the evening before, that may assist the Doctor in
10 terms of the time parameters that he places on the
11 administration, the possible administration of
12 digoxin.

13 THE COMMISSIONER: This is the level
14 of, what page are we on now?

15 MR. OLAH: Page 81 Mr. Commissioner
16 and you will see in the third column, the venous
17 sample is taken at 1745 p.m. on March the 11th.

18 THE COMMISSIONER: 5:45 3.9 you
19 mean?

20 MR. OLAH: It is the 3.9, and I
21 am just wondering whether that would assist the
22 Doctor in terms what outside parameter on when
23 possibly digoxin was administered.

24 MS. CRONK: Q. I am sorry, Doctor,
25 I am not sure that I follow this.

A. I am not sure that I do, either.



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2 THE COMMISSIONER: The point is that
3 apparently if the potassium was 3.9 at 5:45 it is
4 unlikely that the digoxin had been administered at
5 that time.

6 MR. OLAH: Or prior thereto.

7 THE COMMISSIONER: Yes.

8 THE WITNESS: I would agree it is
9 unlikely. I think we have to remember that
10 hyperkalemia is not a consistent finding in digoxin
11 intoxication, it may or may not occur. So I think
12 the normal potassium, the potassium in the normal
13 range and I am talking in generalities now, not
14 this specific case necessarily, but in general, you
15 can't assume because the potassium is normal that
16 there was or was not digitoxin toxicity present,
17 and I just wanted to qualify any conclusions that
18 might be drawn by saying that.

19 THE COMMISSIONER: Possibly the fact
20 that the potassium level did rise at the same time
21 as the digoxin level might indicate perhaps in this
22 particular instance there was a relationship.

23 THE WITNESS: Yes I think that is
24 a likely possibility.

25 MS. CRONK: Q. And to follow my
friend's thought further, Doctor, it is clear that



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2 by 6:30 the following morning, even though the
3 sample taken at that time was slightly hemolyzed,
4 we see a marked increase in what the serum potassium
5 level was?

6 A. Yes. I think there is no
7 doubt looking at the two levels at 6:30 and 7:20
8 that the potassium was really elevated by 6:30 the
9 following morning. That level was a little bit
10 erroneously high because of the slight hemolysis,
11 but I still think it reflected a true elevation of
12 potassium. So I think what I was assuming when I
13 evaluated this, at least looking at the potassium
14 was that if a toxic dose of digoxin was administered
15 it was some time during that 12 to 13 hour period;
16 if that addresses your question.

17 Q. Thank you, Doctor. Doctor,
18 I will return then in a moment to the suggestion that
19 you have raised as to an excessive dose having been
20 given to the child at 9:00 p.m. on the evening of
21 March the 11th.

22 May we deal however for a moment with
23 your own calculations as to what you feel to have
24 been the minimum dose which could have been given to
25 the child to produce the levels that we see in
serum and the tissues. You have done as I understand



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it those calculations and have reported upon them to
Mr. Wiley; do I have that correctly?

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A. I believe so, yes.

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Q. And I refer you, Doctor, to
the last paragraph commencing at page 8 of your
first report to Mr. Wiley. Could you help us first
as to what the minimum dose was that you calculated
in this case?

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A. The minimum dose made from
my assumptions was, and I was talking about an oral
dose in this situation, .7 milligrams which would be
contained in 14 millilitres of the paediatric oral
elixir.

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Q. For the benefit of those,
Doctor, looking purely at your first report at the
moment, as I understand it the actual numbers were
changed in your second reporting letter to Mr. Wiley,
once again because originally you had done your
calculations based on American preparation as opposed
to Canadian.

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A. No, it was an error but it
was a typographical error.

Q. I am sorry.

A. Not because of different
products.



Kauffman, dr.ex.
(Cronk)

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Q. Right. So in any event, Doctor, once the typographical error had been corrected you were talking about a minimum dose of .7 milligrams in a volume of 14 millilitres?

A. That is correct.

Q. And that, Doctor, was with respect to, as I read your report, a dose of the oral elixir?

A. That is correct.

Q. You have also indicated, Doctor, and this is at page 9 of your report, that that dose and that volume of the paediatric elixir would "be quite possible". Can you help me, Doctor, as to what you meant with that statement?

A. Okay. The description of this infant prior to him being described as sick, some time the early morning of the 12th, was that he was taking feedings, was crying lustily and was sucking well. So it seemed to me that it would be quite in the realm of possibility for him to be given this type of volume orally and have him retain it, because his condition seemed to be, according to the description on the chart, of an infant who would be able to swallow it and retain this volume of fluid.



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Q. And Doctor, having regard to the amount that was actually prescribed to be given at 9:00 p.m. on March 11th, .02 milligrams, assuming that your minimum dose was the dose he received, that would be greatly in excess of the amount of prescribed dose, would it not?

A. That is correct. The concentration of digoxin in the paediatric elixir is .05 milligrams per millilitre and he was receiving .02, so that would be contained in a volume of .4 millilitres. So his prescribed maintenance dose would be contained in a volume of .4 millilitres.

Q. Whereas the dose that you are postulating as the minimum would be contained in a volume of 14 millilitres?

A. That is correct.

THE COMMISSIONER: I am a little lost, what is the correction that should be made and where should it be made in this?

THE WITNESS: Oh, in the first partial paragraph at the top of page 9.

THE COMMISSIONER: Yes.

THE WITNESS: The fourth line down.

THE COMMISSIONER: Yes.

THE WITNESS: Says, "With these



1
2 assumptions a dose of approximately .133" and that
3 should be "0.719".

4 MS. SYMES: Could you say that again
5 please.

6 THE COMMISSIONER: 0.133 on the fourth
7 line on the 9th page.

8 MS. SYMES: Could you give me the
9 correct number please.

10 THE WITNESS: The correct number
11 is 0.719.

12 MS. SYMES: Thank you.

13 THE WITNESS: And on the last line
14 of that same paragraph the correct volume is 14
15 millilitres rather than 2.5 to 3.

16 Q. And both of those corrections,
17 Doctor, as I understand it were outlined by you in
18 your second reporting letter to Mr. Wiley?

19 A. That is correct.
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Q. Doctor, may we then just go back for a moment to the calculations you just described for us, and let's look at the amount of the dose that was prescribed to be given at 9:00 p.m. on March 11th.

We know that is described in the medication treatment record as being .02 milligrams to be given orally.

A. That is correct.

Q. In what volume would that be contained in, Doctor, having regard to the forms of elixir that were available?

A. That dose would be contained in .4 millilitres.

Q. All right. And you had concluded, Doctor, that the minimum dose in your judgment that would be required to result in the levels found would be contained in 14 millilitres. Do I have that correctly?

A. That is an estimate given the assumptions I outlined.

Q. Right.

A. It could be a little less, it could be considerably more than that, depending on what assumptions you want to put into the formula.



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3 Q. I take it then, Doctor, if we
4 postulate for the moment that an excessive dose was
5 given accidentally in error to this child at 9:00 p.m.
6 on March 11th, it would have to be a mistake involving
7 a considerably larger volume of digoxin than had been
prescribed?

8 A. That is correct.

9 THE COMMISSIONER: About 30 times.

10 THE WITNESS: Yes, it is an
11 inconceivable error because the individual would have
to use a different container to administer.

12 MS. CRONK: Q. Doctor, you referred
13 a moment ago to the assumptions you made in calculating
14 this dose and told us I think that if the assumptions
15 were an error the dose might be a little bit more or
16 a little bit less.

17 May we turn first to the assumptions
18 which you did make and could you briefly outline those
for us, please.

19 A. The assumptions included
20 that the dose was given orally and since it was given
21 orally 70% of the dose was absorbed.

22 I assume a serum half life of 30 hours
23 again. I assume that distribution had essentially
24 been completed so that the volume of distribution
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I used was 10 litres per kilogram, the same as I had used in other infants.

I picked a mid-point for time within that 12 hour period, and a time that would allow complete distribution, and so I selected 6 hours to plug into the formula.

I assumed because I didn't have any certainty what the real number was, that the concentration at the time of death was 15. I think based on what you told me you could legitimately assume 10.6 or 22, and your numbers will come out a little differently, but I don't think that the basic judgment is any different. And I assumed an elimination rate constant the same as I assumed in the past of 0.231.

Q. Doctor, would we correctly infer from the assumption you made that the dose was given orally, that that was in your view the most likely method of administration?

A. That was my feeling, yes.

Q. You have told us, Doctor --

A. But I think there is virtually an equal probability that it could have been given intravenously some time prior to...

Q. I understand, Doctor, excepting always the possibility of an intravenous large bolus



1
2 dose shortly prior to the onset --

3 A. I couldn't reconcile that with
4 the picture I saw, no.

5 Q. Doctor, as you know,
6 Dr. Spielberg has testified with respect to a number
7 of these children including Kevin Pacsai.

8 He has suggested in his evidence that
9 one possible explanation for Kevin Pacsai's levels
10 both in serum and in tissue and of the fact that he
11 re-established sinus rhythm following his transfer to
12 the Intensive Care Unit is that he may have received
13 an excessive dose of digoxin. This is found,
14 Mr. Commissioner, Volume 55, page 2314.

15 THE COMMISSIONER: Yes, but that is
16 not quite what he said. You haven't finished what
17 he said?

18 MS. CRONK: No, I haven't finished.

19 Q. That is possibility number one.
20 He has suggested as well, Doctor, that another
21 explanation might be that increases in the serum
22 digoxin levels of the child might have occurred as
23 a result of loss of digoxin during life from tissues.

24 I would like to read a portion of his
25 evidence to you in that regard. It is found at
Volume 55, page 2315, sir.



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3 Commencing on the fourth line, this
4 was Dr. Spielberg's evidence, Dr. Kauffman, on this
5 possible explanation:

6 "I think the other possibility has to
7 be considered, that in light of other
8 babies that we have now seen, as well
9 as the published literature that
10 increases in serum digoxin level from
11 tissue loss may have occurred in this
12 baby, thus the baby's serum concentra-
13 tion would have been increased, but
14 the concentration at his myocardium
15 might not have been increased, and in
16 fact might have been slightly decreased.
17 Because again to go to a level of 10
18 or 20 from a level of 1.8 is a very
19 tiny fraction of loss of digoxin as
20 we discussed yesterday. We are not
21 talking about massive digoxin release,
22 we are talking about probably two per
23 cent, maybe three per cent, very, very
24 small amount of release, from mechanisms
25 that again in honesty we don't under-
stand except that we have seen it in
other patients.



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3 "Thus we have a situation where the
4 baby's total body digoxin was the same,
5 but where his serum level in fact was
6 higher. Under those circumstances I
7 find it easier to imagine the child
8 going back into sinus rhythm. The fact
9 that he then reverted to an abnormal
10 rhythm is basically what had been
11 happening to the child all along. In
12 fact the child had tremendous rhythm
13 disturbance and was going up and down,
14 and up and down, and that he finally
15 died from a rhythm disturbance is not
16 surprising.

17 Thus I think the three possibilities
18 that exists in the infant, that I have
19 to at least consider pharmacologically
20 (are) one, accidental or incidental
21 administration of digoxin; and two,
22 abnormal pathophysiology with a rising
23 serum digoxin level as a result of
24 phenomena that again we do not under-
25 stand, but that in fact we see."

I would like to deal obviously,
Doctor, with the second possibility that Dr. Spielberg



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2 has advanced, and that is what he described as the
3 abnormal pathophysiology of this child could have
4 accounted for a redistribution or loss of digoxin,
5 if you will, from tissues of the child, during life
6 to serum accounting for elevated serum levels.

7 I would like to refer you as well,
8 Doctor, to page 9 of your own reporting letter to
9 Mr. Wiley, the second paragraph dealing with Kevin
10 Pacsai in which you had said:

11 "The inherent dysrhythmia of this
12 infant - "

13 A. I'm sorry, where are you?

14 Q. Page 9 of your first reporting
15 letter to Mr. Wiley, and this is the --

16 A. That doesn't --

17 Q. The second paragraph.

18 A. Oh, the top of the page, okay.

19 THE COMMISSIONER: The first full
20 paragraph.

21 THE WITNESS: Yes.

22 MS. CRONK: Q. "The inherent
23 dysrhythmia of this infant probably
24 made him exquisitely susceptible to
25 digoxin-induced fatal arrhythmias. I
am aware of no evidence that no other



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"medication or other agent was administered which may have contributed to this child's death."

That was your opinion at the time I take it?

A. That is right.

Q. Doctor, in these circumstances and having regard to the opinion expressed by Dr. Spielberg and your own knowledge of this child's condition and disease state, could in your judgment his particular pathophysiology account for both the circumstances of his death and the digoxin levels found in tissues and in serum?

A. I don't think so. At the time I wrote this report I was not considering the second hypothesis that Dr. Spielberg advanced. I subsequently have, of course, considered that and thought about it.

What I meant in the first sentence of the paragraph you just read really had no meaning in relation to Dr. Spielberg's comments, and maybe I should address what I meant in that sentence.

This baby clearly had an underlying dysrhythmia problem. That was documented on admission to the other hospital, so with or without the digoxin he had a basic underlying problem.

Babies with various kinds of dysrhythmias, including the one this infant apparently had, are much more susceptible to drug induced arrhythmias which can be life threatening, and digoxin of course can do that.

So what I was saying here is that this in fact could have had a life threatening arrhythmia induced by digoxin at lower concentrations than you might - than would produce a fatal arrhythmia in a child who had a normal heart. That was all I was saying.

Q. I see.

A. Now in response to the comments from Dr. Spielberg's testimony which you just read, I said I wasn't considering that hypothesis at the time I dictated this report. It was something that I had never thought about.

Subsequently I have gone back over this case with that in mind and attempted to see whether I not could fit that concept into this particular case. There are several factors that make it difficult for me to agree with Dr. Spielberg's hypothesis in this specific case. One is that although this child had a life threatening arrhythmia at McMaster Hospital and was in severe acidosis, he recovered



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2 rather rapidly and was apparently physiologically
3 normal at certain times subsequent to that event.

4 He had an anatomically normal heart
5 at autopsy. He had normal blood gases when they were
6 measured following that initial event when he
7 almost died.

8 He had normal potassium level when
9 it was measured on his admission here and then it
10 subsequently went up over the next 13 hours.

11 At autopsy there was no description
12 if I remember correctly of any significant myocardial
13 damage so it is difficult for me in the absence of
14 an anatomically abnormal heart, and the absence of
15 acidosis and hypoxia, in the absence of evidence of
16 myocardial damage at autopsy, to accept a hypothesis
17 with any degree of probability that explains tissue
18 redistribution out of the myocardium to explain an
19 elevation in the serum.

20 I think one has to consider it and
21 consider it seriously, but I just can't reconcile it
22 with the facts as I see them.

23 Q. Doctor, I take it that you
24 would agree that there can be cases where the particu-
25 lar disease state of the child or his or her patho-
physiology, to use Dr. Spielberg's language, could



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2 well account for an elevation in serum digoxin levels
3 during life. Would you agree with that?

4 A. A general answer to your
5 question, I think that is possible, yes.

6 Q. And, Doctor, having regard
7 to the particular dysrhythmia from which this child
8 was suffering that you yourself described as being
9 (a) both inherent and (b) rendering him in your
10 language exquisitely susceptible to digoxin toxicity,
11 is not possible, Dr. Kauffman, that the underlying
12 cardiac condition of this child was sufficient to
13 cause tissue damage during life so as to cause that
kind of release of digoxin?

14 A. I suppose it is possible,
15 but there is no evidence of it from the autopsy
16 report that I am aware of, and I would expect to
17 see some evidence at least microscopic that that
had occurred.

18 Q. Yes.

19 A. Maybe we can look at the
20 autopsy report.

21 Q. I would ask you, Doctor, if
22 you would, to turn to page 94 of Pacsai's medical
23 record. That is his preliminary autopsy report. The
24 final autopsy report, Mr. Commissioner, is Exhibit 106A.
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I don't know whether --

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THE COMMISSIONER: I think it is
right with it.

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MS. CRONK: Q. Doctor, we see
firstly confirmation that at autopsy --

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A. I'm sorry, where are you?

8

Q. Page 94.

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A. You are not on the exhibit?

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Q. No, on page 94, the second
paragraph under the short history.

11

A. Okay.

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Q. We see confirmation that at
autopsy the child's heart was anatomically normal.
Do you see that?

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A. Yes.

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Q. And then continuing with the
description of what was seen at gross autopsy,
there was presence of congestion in several organs,
there were petechial hemorrhages of the thymus and
recent hemorrhage of falx cerebri are most likely
related to hypoxia.

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A. Right.

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Q. And then the discussion is
about cultures.

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A. Right.



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Q. And the absence of any evidence
of infection.

Could not the hemorrhages reflected
in the gross autopsy and indeed in the final autopsy
report constitute evidence of damage to the muscle
or tissue of this child potentially sufficient to
cause dislodging of digoxin from tissue?



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A. I don't think ante mortem. I think those are terminal agonal changes that are commonly seen in autopsy related to the hypoxia and acidosis that supervenes during the resuscitation and the death of the individual.

Q. Well, Doctor, I grant you that this ---

A. I don't think that we know that these were ante mortem changes.

Q. Doctor, I grant you that the pathology findings reported in this case on this aspect of it are quite different than for example we have seen in the case of Allana Miller where specific mention was made of extensive resuscitation trauma. However, I draw your attention to the findings under Anatomical Diagnoses and, in addition to the hemorrhages to which I have drawn your attention, mention is made of an infarction, described as an old one, to the left kidney cortex.

A. This is still on page 94?

Q. Yes, still on page 94, Item No. 6, Doctor, under Anatomical Diagnoses.

A. Yes.

Q. There is evidence of an old infarction to the left kidney and as well of stress on



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the thymus and presumably effect on the organ itself from that stress. Could either of those pathological findings in your view account for dislodging of digoxin from the tissues of the child?

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A. I suppose it is possible. I think it is somewhat unlikely. During that three-day period the infarction is described as old. I don't know what is meant by that, whether it is days or weeks. This type of thing happens in kidneys sometimes due to reduced flow through the vessels to the kidney and may have indeed happened the four or five days previously when he was in shock at McMaster. The thymus in babies who are stressed commonly decreases in size over a period of time and I have no idea what the digoxin content is in thymus, I have never seen any data in which that was measured. But I suspect that the thymic change was a change that took place over a period of weeks, days to weeks prior to his, even maybe prior to his admission to McMaster because he was sick for several days even before he went in there and is a response to the illness and the stress that he sustained during that five, six day period.

Q. Doctor, you are familiar as I understand it with the case of Gary Murphy, a child who died at The Hospital for Sick Children in April of this year?



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A. Yes, I am.

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Q. Indeed, as I understand it you

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testified at the inquest of that child?

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A. Yes, that is correct.

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Q. Is that correct, Doctor?

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A. That is correct.

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Q. Doctor, I would like to draw

9

your attention to certain portions of your evidence

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from the inquest of Gary Murphy. Do you have a

transcript of your evidence, Doctor?

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A. I have a copy, I think it is

12

the same.

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Q. I would ask you if you would,

Doctor, to turn to page 39. Do you have that, Doctor?

14

A. Yes.

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Q. Doctor, as I understand it, you

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were asked at the inquest to outline what you felt

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might be possible explanations for the post mortem

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serum digoxin levels found in Gary Murphy and that

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you in fact did outline a number of possible

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explanations but that you preferred one and expressed

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a preference in terms of likelihood for one as opposed

to the others. Do I have that correctly?

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A. That is correct.

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Q. And am I correct as well, Doctor,

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that the post mortem serum levels on this child were considerably elevated; indeed, at the Centre of Forensic Sciences they were as high as 32 nanograms per gram, although, the readings at The Hospital for Sick Children were 18.7, is that correct?

A. That is correct.

Q. All right. Doctor, your fifth and preferred hypothesis in this case, as I understand it, is recorded in outline at the top of page 39 of the transcript of your evidence. It reads:

"The fifth hypothesis or theory is that the gradual worsening of his cardiac condition, the continuing and progressive damage to his heart muscle, his increased lack of oxygen, which is called cyanosis, his reduced output of his heart, cardiac output, the profusion of his tissues resulted in damage to these tissues either functionally or in some cases by the autopsy actual cell death of some tissues, thereby releasing bound digoxin into the serum compartment or into the extra saline fluid which would then diffuse back into the serum."



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A. Saline is a typographical error,
it was extracellular.

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Q. And you continue:

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"There is very little known, if any-
thing, in the literature about the
effects of these kinds of severe
physiological derangements of the
binding of digoxin and, so, it is
difficult to present objective or
conclusive evidence to support this
hypothesis but from what is known
about the characteristics of the
binding sites I discussed this morning
and the nature of the binding of
digoxin to this material, this is
certainly pharmacologically reasonable
and rational."

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Doctor, that was your preferred
hypothesis or explanation for the elevated levels
found in Gary Murphy, was it not?

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A. That is correct. I think that
to place that in context it is important to note the
qualifications I put on that before I offered it.
Gary Murphy was a very puzzling case to me and I wasn't
alone in that. In looking at Gary Murphy he was, as



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you know, I think six or seven months old at the time he died; he may have been a little older than that, I don't recall specifically. He had had severe cyanotic heart disease from the time of birth. He had an extremely unusually complex type of congenital heart disease or complex of congenital anomalies which caused him to be severely cyanotic from birth.

He progressively deteriorated during the several weeks prior to his death to the point where the surgeons and the cardiologists had apparently told the parents that there really wasn't anything curative that they could offer him and apparently from the chart the decision had been made to not be heroic with him since he could not be cured, keep him comfortable and not take the usual heroic measures to preserve his life. Because of that there is very, very minimal documentation on his chart regarding laboratory studies, including blood gases, electrolytes, blood urea nitrogen and digoxin levels because I suspect a minimal amount of manipulation was being carried out with this child simply to reduce his suffering.

So, we were handicapped in trying to assess his case because of a posity of objective data. In looking at the entire picture it was difficult then



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2 to come up with any clear explanation for the post
3 mortem digoxin concentrations that were observed in
4 this child.

5 So, looking at all the possibilities
6 I couldn't explain it by renal failure, I had no data
7 upon which to explain it by acidosis alone, although,
8 I thought that he was probably acidotic in the hours
9 prior to his death because of his severe and
10 increasing hypoxia. So, I had to consider all the
11 possibilities and the other four possibilities that
12 I could think of, I couldn't reconcile with what
13 information I did have and this was the only
14 explanation that I could think of that I thought could
15 fit the picture but I was never totally comfortable
16 with it and I think I made that clear in my testimony
17 at that time.

18 Q. I'm sorry, Doctor, I didn't
19 mean to imply that you were saying with certainty or
20 certitude that that was the explanation for that
21 child's levels.

22 A. I understand that, but I didn't
23 want to let that misconception exist either. I think
24 what I said in that testimony specifically about that
25 concept has to be interpreted in the context of all
the caveats I placed on it.



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Q. Well, Doctor, my point to you is simply this. Isn't the hypothesis which you preferred in the case of Gary Murphy in fact very similar to, if not identical, to the hypothesis, if you will, proposed by Dr. Spielberg as a possible explanation for Kevin Pacsai's levels? Aren't we talking about the very same thing?

A. As I understand his testimony, I think it is essentially the same, yes.

Q. All right. And aren't there as well, Doctor, a number of similarities between the case of Gary Murphy and Kevin Pacsai; first, both had elevated post mortem digoxin levels on blood specimens?

A. Yes. In reviewing the charts that's about the only similarity that I can see.

Q. Well, Doctor, let me perhaps suggest some others to you.

A. Okay.

Q. All right. Both had, as you have told me, an elevated post mortem serum level, and I suggest to you that the actual concentrations measured 26 nanograms post mortem as compared to 32 nanograms in Gary Murphy's case or 18 if you take The Hospital for Sick Children level, are, in a quantitative sense, relatively similar?



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A. I don't think we can differentiate
between them really.

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Q. And as well, Doctor, in neither
case, as I have understood your comments just now
about Gary Murphy, were you able to see any evidence
of renal failure? That was not an explanation in
Gary Murphy's case?

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A. That is correct.

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Q. And that is not in your judgment
an explanation for Kevin Pacsai?

A. It is not an explanation. They
both appeared to have normal renal function except we
didn't have the data in Gary Murphy close to the time
of his death like we do in Kevin Pacsai.

(2)

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Q. And you are referring to now ---

A. We just didn't have the infor-
mation.

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Q. You are referring now to the
blood gases or the BUN?

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A. Blood urea nitrogen or the
creatinine.

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Q. All right. Doctor, as well, both
of those children had underlying cardiac diseases of
some severity?

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A. That is correct, but the heart



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disease was extremely different, totally different.
You can't lump all heart disease in one category.

Q All right. Well, Doctor, what I'm suggesting to you is, and I would like your opinion on this matter, having regard to the situation that you were most familiar with, equally familiar with, that is, Gary Murphy and your knowledge of Kevin Pacsai's clinical condition and the nature of his disease state, is it not possible in your view that Kevin Pacsai's pathophysiological condition could account for the elevated levels of digoxin that we see in that child?

A I don't think so. Their pathophysiological conditions were very, very different. For example, Kevin Pacsai was much younger, Gary Murphy was six or seven months of age, and I can't remember specifically, but the major difference was that Gary Murphy's problem was a very complex anatomical lesion which caused him to be severely cyanotic all his life. He never had enough oxygen going to his heart.

In contrast, Kevin Pacsai had no anatomical abnormalities in his heart. He did not have hypoxia except the times when his cardiac output severely fell when he was so sick at McMaster. He



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has no other times when he has documented cyanosis.

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In fact, Kevin Pacsai had normal heart output when his heart was beating normally.

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So that the two types of heart disease are so dissimilar. In my mind at least they really can't be compared at all, it is like comparing apples and oranges, or maybe no more different than that.

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Q All right, I see, Doctor, thank you, that's helpful.

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Doctor, I am obliged to ask you if Gary Murphy had died in March of 1981 would his death have been one that you would have assessed as possibly involving digoxin intoxication?

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A I think he would have been assessed during that period of time because, as I understand it, every baby who died during that period of time was being very carefully looked at and evaluated.

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Q Doctor, in the course of the assessment, had you been reviewing Gary Murphy's case at that time for that purpose, would you, as best you can tell today, have then felt that digoxin intoxication was the preferred explanation for his post mortem serum levels?

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MR. HUNT: I wonder, Mr. Commissioner,



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if that kind of a question is really helpful at all to this Inquiry. First of all, to ask this witness to try to put something that was in a totally different context ---

THE COMMISSIONER: Well, he may not be able to, and I don't know how much help it is but I don't see anything wrong with the question, that is, if you can answer it, Doctor, in the state of your knowledge at that time as opposed to your knowledge now and if you can, say, would you be likely if you had been on the scene - is it on the scene? He wasn't on the scene of course until 1982 anyway.

THE WITNESS: No, I came in late in the course of the events.

MS. CRONK: I suppose properly speaking, the question I was struggling to put, Mr. Commissioner, and badly, is that if this had been one of the children amongst the 36 that you reviewed when you reviewed the others for Mr. Wiley, are you in a position to tell us whether you would have felt that digoxin intoxication likely contributed to his death?

THE WITNESS: Before I answer that I'm going to refresh my memory as to the criteria I was using for making those classifications, if I may.

MS. CRONK: O. All right.



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A. Because I'm not sure what I would have done then at that time with what I was aware of at that point in time. The best guess I can make is that I probably would have rated him - are you asking in terms of - I had better make sure I understand your question. Are you asking me in terms of evaluating him as I have the others in the Police report?

Q. Yes I am, Doctor.

A. Okay.



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Q. If he had been one of this
group that you looked at all 36 --

THE COMMISSIONER: We are really
looking at whatever date this is in 1982 I think you
said.

MS. CRONK: January of this year, sir.

THE COMMISSIONER: January of 1983.

MS. CRONK: Was the second reporting
letter.

THE WITNESS: December and January.

THE COMMISSIONER: Yes. All right.

THE WITNESS: I think I would have --

THE COMMISSIONER: Before you go
any further --

THE WITNESS: Yes.

THE COMMISSIONER: -- it is legitimate
for you to say you don't want to answer that question,
but if you want to answer it I certainly want to have
you answer it.

THE WITNESS: I don't mind answering
it but I really don't know what I would have done at
the time.

MS. CRONK: Q. I think that is the
answer.

A. If I was forced to say you
have got to tell me something, I could give you an



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answer.

THE COMMISSIONER: You are not forced, but if you want to give us an answer.

THE WITNESS: I think it is very speculative because I really don't know how I might have evaluated it at that point in time. It is hard to put yourself back in that frame of mind a year later.

MS. CRONK: Q. I think the matter is best left there, sir.

May we take our break?

THE COMMISSIONER: Yes. We will take 20 minutes.

MS. CRONK: Thank you.

THE COMMISSIONER: Oh, Miss Cronk, we have to make this an exhibit. The abstract from the proceedings, Exhibit 271.

--- EXHIBIT NO. 271: Abstract from proceedings of International Society for Clinical Pharmacology, July 1983.

--- short recess.

--- Upon resuming.

THE COMMISSIONER: Yes, Miss Cronk.

MS. CRONK: Thank you, sir.

Q. Doctor, may we turn now please to the case of Kristin Inwood. In our discussion with



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respect to this child commences at page 11 of your reporting letter, your first reporting letter to Mr. Wiley.

As I understand it, doctor, when you delivered your first reporting letter you were of the view that the available digoxin levels of and in themselves were inconclusive regarding digoxin toxicity in this child; do I have that correctly?

A. That is correct.

Q. And you had available, so that we are clear, at that time the digoxin concentrations which had been measured in fixed heart tissues in Kristin Inwood?

A. That is right.

Q. And those levels, doctor, as you may recall I suggest were 230 nanograms per gram in the left ventricle; and 300 nanograms per gram in the septum dealing simply with the heart tissues. Does that accord with your recollection?

A. In the fixed tissues, right.

Q. And those levels I suggest further, doctor, are both within the range of levels reported by Mr. Cimbura in cases of fatal poisoning but as well are within the range reported by him for persons on digoxin therapy?



H4

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A. That was his report, yes.

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Q. Is that correct, doctor?

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A. That is correct.

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Q. If we look at the actual levels, doctor, that is the 230 nanograms in the left ventricle and the 300 in the septum, I suggest that the concentrations are in fact high.

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A. They are higher than most of the fixed tissue specimens were, yes. That would lead you to believe --from talking to Mr. Cimbura I assumed that his true digoxin levels in fixed tissues represented the least it might have been with no way of knowing how much more than that it might have been at death.

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Q. You are suggesting these in fact might have been higher at death?

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A. I would expect, yes, they were, the fixed tissues tend to leach out into the fixative and so that concentration in the tissue decreases with time as it sits in the fixative. So these concentrations would have represented the least it could have been at death, and very likely they were actually higher than that at death, but how much higher I have no way of knowing.

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Q. Am I correct, doctor, that when we compare the concentrations reported on Kristin



H5

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2 Inwood's fixed heart tissues quantitatively the numbers
3 are higher than they are in the fixed tissue concentra-
4 tions on any of the other children that we have looked
5 at?

6 A. That is correct.

7 Q. And, doctor, does that neces-
8 sarily imply with respect to this child that there was
9 some time available prior to death for distribution of
10 digoxin if it was administered to the child from the
11 serum to the tissues?

12 A. Yes, I think that is the case,
13 yes.

14 Q. Doctor, were you also aware at
15 the time of doing your first reporting letter to Mr.
16 Wiley of the ante mortem digoxin level which had been
17 measured on this child the day prior to her death,
18 and that level was 2.6 nanograms?

19 A. Yes, I was aware of that.

20 Q. Doctor, on the basis of what
21 was known to you at the time that you delivered your
22 first reporting letter to Mr. Wiley what was your
23 overall conclusion regarding the involvement of digoxin
24 in the death of this child?

25 A. I felt that, as you said, the
fixed concentrations, although they were higher than



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the other fixed tissue concentrations in other patients, were still inconclusive in terms of whether or not digitalis toxicity had been related to the death.

I also was aware that the type of heart disease this child had is not uncommonly associated with sudden death. So at that time I felt that in the face of the normal digoxin concentration the day before, and the fact that digoxin had ostensibly not been ordered for the child following that, that the probability of digoxin being responsible for this infant's death was low.

Q. I take it it was still a possibility at that time that you were not prepared to discount entirely?

A. I was not prepared to totally discount it but I thought the possibility was low.

Q. And, doctor, as I understand it, subsequent to the delivery of your first reporting letter you became aware of a post mortem serum sample that had been tested by Mr. Cimbura, and it is recorded to have a digoxin concentration of 491 nanograms per millilitre; is that correct?

A. Yes, I was subsequently made aware of that.

Q. And did that new information,



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doctor, between the time of delivery of your first report and your second cause you to alter your opinion in this case?

A. Yes, it did.

Q. In what respect?

A. I thought it significantly increased the probability that this child had indeed, that her death was indeed related to digoxin intoxication.

Q. Doctor, I ask you if you would, please, turn to page 3 of your second reporting letter to Mr. Wiley.

A. I have it.

Q. Do you have that, doctor?

A. Yes.

Q. And I draw your attention to the last sentence of the first main paragraph in which you say:

"The high serum digoxin concentration in the frozen post mortem venous specimen..."

A. I'm sorry, I am not with you.

Q. I am sorry. Actually it is all one paragraph and I apologize, doctor, about two-thirds of the way down the paragraph.



Kauffman
dr.ex. (Cronk)

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A. Yes.

Q. You see where it says, "However,
even if one assumes..."

A. Yes.

Q. Would you go please to the
next sentence.

A. Okay.

Q. "The high serum digoxin concen-
tration in the frozen post mortem
venous specimen is a very important
piece of data and strongly supports
the theory of death due to digoxin
intoxication which was originally
based on the high fixed tissue
concentrations and the hyperkalemia
found the morning of death."

I suggest to you, doctor, that the
language of that section of your report would seem to
indicate that you had in the absence of the knowledge
of the blood sample concluded that digoxin was likely
involved in the death of this child; is that correct?

A. I considered it as a possibility.
Hyperkalemia was a factor, but the problem with the
hyperkalemia was as I recall her pH was low, it was
7.14 or something like that close to the time that



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potassium was drawn. So I couldn't be certain if the hyperkalemia was -- might have been related to digoxin intoxication or to her acidosis. Although I had to take it in, I couldn't ignore it, I had to take it into account. I had to take into account her clinical course, but I did not have strong, at that time, in the first report, I didn't have strong digoxin data to support that theory so I had much less confidence in that theory than I did after I was made aware of the serum concentration of 491.

Q. Doctor, when you refer to the hyperkalemia in this child, are you referring to the serum potassium level which I recall was 7.3 on the morning of her death?

A. That is correct.

Q. Doctor, with respect to this post mortem blood specimen, you indicate in the first sentence of your report to Mr. Wiley that you had become aware of it and that it was a sample from the sagittal sinus which was apparently obtained from the infant at the time of autopsy and remained frozen for some months prior to performing a digoxin assay on the sample.

Can you tell me first, doctor, what the source of your information was that the sample



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was from the sagittal sinus of the child?

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A. This was information provided to me by either Mr. Cimbura and/or the Crown Attorney staff, I don't remember exactly who the individual was. This was during a meeting that I had when I was discussing my original report to them.

Q. Doctor, I tell you that there is some doubt on the evidence adduced in these proceedings to date as to the source of that sample. One suggestion that has been raised is that it may have been taken by Dr. Glen Taylor at autopsy from the inferior vena cava of this child. Were that the case, and were it not to have been taken from the sagittal sinus, would that affect your conclusions or alter your thinking in any way with respect to the importance of the sample result?

A. I really don't think that would have any influence on my views of that sample.

Q. Doctor, you have said as well that the sample according to your information had remained frozen for some months prior to performing the assay. Once again, what is the source of your information in that regard?

A. As I recall it was the same source but I don't remember the individual, this was



Kauffman
dr.ex. (Cronk)

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information that was obtained during a group meeting.
At that time I was getting all my forensic information
of course through Mr. Cimbura or somebody on his
staff, so I don't remember exactly who gave me that
specific information.

Q. Doctor, what significance, if
any, do you attach to the fact that the sample may
have been frozen for a period of several months?

A. Well, in view of the extremely
high concentration that was measured, and in view of
questions about how it had been stored, I had to think
of possibilities in terms of how the sample was
handled that might have accounted for, at least in
part for the high concentrations. Actually I didn't
mention this specifically in this paragraph, but as
I recall, and this is only my recollection a year
later, but as I recall that discussion included the
possibility that the sample might have been frozen,
or it might have been refrigerated. As I recall the
possibility was raised that maybe the container of
that sample had not been capped so that it was open
during the storage time. There were a lot of un-
certainties about exactly how the sample had been
obtained and cared for up to the time it was found and
then eventually assayed. So I thought that there was



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a possibility with all of that uncertainty that the concentration might at least in part be accounted for by artefact induced by the storage conditions.

One major artefact if it had been stored open for a period of months, or even in the refrigerator, is the possibility of evaporation which would reduce the volume of the sample if that occurred, and have the effect of artefactually increasing the concentration of digoxin in the sample. So I had to take that into consideration, that possibility, when I evaluated that number.

Q. And, doctor, we see from your comments to Mr.Wiley that you assumed that the actual concentration at the time of death of Kristin Inwood could well have been one-tenth the measured concentration in the frozen sample. I stop for a moment. Was that assumption a result, doctor, of the concerns that you had regarding both the purity and the nature of the storing of the sample?

A. Yes, that is correct. I was trying to determine in my own mind what the least the concentration might have been when the sample was fresh. And that is why I used an extreme number of one-tenth, to say even if we assumed an increased, extreme amount of evaporation, what would the



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concentration still be?

Q. Were you attempting, doctor,
to assume then the worst conditions that might have
applied, the worst effect that might have resulted
because of the conditions of storage?

A. That was my idea, yes.



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Q. And taking, Doctor, then a tenfold amount as the likely or possible in which you thought it to be, likely or possible level at the time of death, what conclusions did you reach regarding the implications of that concentration?

A. Making that assumption I assumed a situation where the concentration might have been a tenth of that which would be 49 micrograms per millilitre, and I thought this was still a high concentration and could have been associated with digoxin, a contribution of digoxin to the infant's death.

Q. That would make it, Doctor, on the pure mathematics, approximately 49 nanograms at the time of death.

A. That is right.

Q. Are you in any position on the information available to you, Doctor, to express in your opinion as to the likelihood that that was in fact close to the quantitative level at the time of death?

A. I think - my opinion is that that would be approximately - that would approximate the least it might have been.

Q. Doctor, on the basis of



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I.2 the information that was available to you were you as well able in this case to make any estimates regarding the possible time and route of administration and likely dose of digoxin that may have been administered to the child?

A. Pardon me. I just want to review my notes before I answer you.

My feeling was that assuming this was a very high serum concentration, I didn't think it was actually 491 because I couldn't reconcile that with any type of feasible dose but I thought it was probably quite high. But assuming that I had to assume, and also based on the unusually high concentration in the fixed tissues even for fixed tissues, and the hypokalemia, if I accepted that as being related to digoxin intoxication rather than the doses alone, I felt that that composite picture suggested not only a large dose but probably within an hour or two prior to death, or terminal event, with relatively little tissue distribution.

Now that is referring primarily to the serum concentration. If you are going to explain a very high serum concentration like that you have to say to administer it in a feasible volume, a mechanically feasible volume, you would have to give it and



I.3

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2 have relatively very little distribution prior to the
3 serum sample being obtained.

4 On the other hand what bothered me
5 about that was the relatively high tissue concentra-
6 tions for fixed tissues. If I took that into account
7 I had to consider a rather high dose with some degree
8 of equilibration of the tissues which set the time
9 back a little further from death than what I would
10 posit with the serum concentration alone, and I
11 really couldn't be more specific than that because
12 there just wasn't enough information to tie it down
any more closely.

13 Now really I think if we accepted the
14 tissue concentration was compatible with some distri-
15 bution and viewing the relatively high serum concentra-
16 tion, regardless of what dilutional factors you want
17 to put on, I think we have to propose the dose if
18 digoxin was given being given some time prior to an
19 hour before death and maybe even longer than that,
20 but again if a very large dose was given the infant
21 might not survive for a number of hours with a very
22 large dose so that that limits your outside figure to
some degree.

23 Q. Doctor, if you hypothesize
24 the most likely possibility a dose given approximately
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I.4
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2 an hour or thereabouts prior to I take it the child's
3 agonal symptoms, critical symptoms?

4 A. Well, we are dealing with I
5 suppose you could define it that way or the time that
6 the child was finally pronounced dead. It is hard
7 to define death in these children because many times
8 they were in the process of dying over a period of
9 30 minutes to several hours. So I can't really tie
10 it down real tightly.

11 I would say it was at least an hour
12 before tissue distributions ceased which would be
13 when cardiac output fell to such a low level the
14 tissues weren't being profused any more or some
15 time prior to that.

16 Q. Does that then, Doctor,
17 necessarily rule out in your judgment the possibility
18 of oral administration?

19 A. It doesn't totally rule it
20 out, no.

21 Q. Well assuming, Doctor, --

22 A. I think it is unlikely because
23 of the size of the dose that would have to be given
24 to produce this total picture.

25 Q. Given what you have told us,
Doctor, about absorption rates and the time necessary



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with an oral dose for distribution to in fact take place from the tissues, - from the serum to the tissues, is it in your view remote, a remote possibility that that was the method of administration, or is it a good candidate?

A. No, I think it is a much more remote possibility than intravenous administration.

Q. Doctor, one of the matters raised by Dr. Spielberg with respect to this child had to do with the sequence of events that are recorded in the medical record as having occurred.

Do you have Exhibit 113 there, Doctor?

A. Yes.

Q. I would ask you to turn to page 63 if you would, please.

Do you have that, Doctor?

A. Yes, I have page 63.

Q. Doctor, the progress note on that page indicates that the child was given a dose of Lasix at approximately 11:10 p.m. on the evening of March 12th after which she is recorded to have voided urine. And then at 2:00 p.m. in the morning it is indicated that the monitor strip showed abnormalities, that the team leader, the nursing team leader was notified, a resident was called, Lasix



I.6

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2 in the amount of 3 milligrams was given IV by the
3 resident once he arrived; tachycardia resulted,
4 200 beats. The baby came I take to be very irritable
5 and at 2:30 a Code 25 was called and the child was
6 not able to be revived.

7 Dr. Spielberg has testified, Doctor,
8 that given those, the recorded sequence of those
9 events, that it is possible that digoxin either
10 deliberately or accidentally was administered to
11 this child in lieu of Lasix some time between 2:00 and
12 2:30 in the morning. That is prior to the calling
13 of the Code 25.

14 Is the possibility of a medication
15 error with this child a matter, Doctor, that you
16 considered in preparing your reports?

17 A. Yes, it was. In fact that
18 had to be considered in virtually each of the cases.

19 Q. Assuming then, Doctor, that
20 a dose of digoxin in the amount of 3 milligrams, the
21 amount intended to be given for Lasix, assuming that
22 that amount of digoxin was given between 2:00 and
23 2:30, and that the child actually died some time after
24 2:30 a.m., could a dose in that amount given within
25 that time frame in your judgment account both for
the post mortem serum level found and the concentration



I.7

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in this child's fixed tissues?

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A. You are talking about the 2:00

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to 2:30 a.m.?

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Q. I am.

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A. Not the 11:10?

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Q.' No, I'm talking about the

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2:00/2:30 time frame.

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A. I don't think so. I should

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do some arithmetic for you before I answer that
definitively.

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I think time-wise it doesn't fit the

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picture for me. I have a hard time reconciling that

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time frame with the tissue distribution.

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There may be another problem here in

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terms of the size of the dose of digoxin that might
have been given assuming this volume.

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If you don't mind I'll do some

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arithmetic.

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Q. No, please, Doctor. I think

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the matter is of some importance.

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A. I think we have got 3 milligrams

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of Lasix was what the child was being given, and that

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would be 0.3 millilitres, so we have to see how much

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digoxin if the error was made, how much digoxin would

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be contained in three-tenths of a millilitre.

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I.8

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3 If we assume the most that it would
4 contain, that would be the adult intravenous prepara-
5 tion, so that would have contained .25 milligrams per
6 ml in the adult preparation. So if we divide - well,
7 it would be three-tenths of this. That would be
8 .075 milligrams.

9 So if that error was made and if the
10 appropriate volume - the error simply was that the
11 wrong medication was drawn out but the appropriate
12 volume, this is the amount of digoxin that would be
13 contained in that. Then we need to look and see what
14 this baby weighed. I think it was $2\frac{1}{2}$ --

15 Q. $2\frac{1}{2}$ kilos.

16 A. $2\frac{1}{2}$ kilos. So let's assume -
17 in this situation we are talking very little,
18 essentially no distribution because the dose was
19 given shortly before death, so we will assume a small
20 volume of central compartment volume distribution to
21 the tissues. It would be 1 litre, approximately
22 1 litre per kilogram which would be 2.5 litres, and
23 if we put this amount of digoxin into this volume
24 we will get - that would give us a concentration of
25 30 nanograms per ml at the most.

So I don't think - this doesn't fit
the picture very well for several reasons: one is



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2 it doesn't account for any digoxin in the tissues,
3 and secondly it doesn't account for the post mortem
4 serum concentration.

5 Q. Then can we deal with the
6 latter issue first, Doctor? If we assume that this
7 kind of an error was made, achieving a concentration
8 that you have calculated to be 30 nanograms at the
9 most per millilitre, if we take into account first of
10 all a multiplier within a range that is acceptable to
11 you, and if we, for example, suggest that the multi-
12 plier in this case was 3 or 4, taking the outside
13 4, that level could elevate in known ranges to
14 120 nanograms post mortem. Would that be correct?

14 A. That is possible.

15 Q. And if we take then, Doctor,
16 further into account the possible effect of
17 dessication or evaporation or a contaminant in the
18 sample as you did in considering the 491 nanograms,
19 is it not also possible that further elevation from
20 120 could be fully accounted for by the storage
21 conditions that applied or could have applied with
22 respect to that sample?

22 A. Yes, I think that is possible

23 Q. That we could go from 120 to
24 491 by virtue of those conditions?
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A. If we look at serum itself
I think we could fit it to this scenario of an error
like this.

My problem is I have a hard time
reconciling it with the tissue concentrations.

Q. Right. As I understood it,
Doctor, the assumption you made in doing these
calculations was that it was a central compartment
calculation, very little distribution time from the
serum into the tissues; is that correct?

A. That is correct.

Q. All right. Doctor, assuming
again that the concentration was 30 nanograms per
millilitre, is that amount consonant with what you
understand to be a therapeutic dose of digoxin, a
maintenance dose?



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BB/cr

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A. Dose or concentration?

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Q. I am sorry, the dose that

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you estimated - well, the volume of digoxin you
described was .075 milligrams.

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A. That's the dose.

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Q. That's the amount of the

7

digoxin?

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A. That's the amount of the

9

digoxin.

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Q. Is that amount consonant

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with what you would consider to be a maintenance
dose of digoxin?

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A. Not a maintenance dose, no.

13

It would be about three times a maintenance dose.

14

Q. Thank you, Doctor. One

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final matter with respect to Kristin Inwood, Doctor.

16

There has been evidence led before the Commission

17

suggesting that this child in fact received a dose

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of digoxin prior to her death that was intended for

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another patient, a medication error in fact was made. She

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received in that regard - I am not sure that I have

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the amount at hand - but the incident took place,

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Doctor, at 5:30 a.m. on the 12th of March and it

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resulted in a digoxin level of 2.6 nanograms at

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9:00 a.m. that day.

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2 THE COMMISSIONER: That's the amount
3 intended for some other child, I think it was the
4 Pacsai child.

5 MS. CRONK: I think that is correct,
6 Mr. Commissioner.

7 THE COMMISSIONER: So, we can easily
8 discover the amount if you want to have it by looking
9 at the Pacsai chart.

10 MS. CRONK: Q. Well, it may be
11 relevant for you, Doctor. My question on this matter,
12 sir, is simply this. Having regard to the fact that
13 we know and have a concrete example that at least
14 one medication error took place with Kristin Inwood,
15 does that affect your views as to the likelihood that
16 another could have occurred in exactly the same way
17 that you have outlined it here so as to account
18 for the levels that were seen in her blood post
19 mortem?

20 A. I can't really say that one
21 medication error changes the probability of another
22 medication error. I think that the probabilities
23 of medication errors, of individual medication
24 errors are probably independent, the probabilities
25 are independent of each other, so, I can't really
say that the fact that a medication error occurred



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2 earlier would make it more or less likely that
3 another medication error would have occurred later.

4 Q. Doctor, the amount that she
5 received in error was apparently .02 milligrams, is
6 that correct?

7 DR. GILMOUR-BRYSON: I think it is
8 .032 if it is Pacsai.

9 MS. CRONK: Q. I am sorry, I will
10 have to check that and give it to you later in the
11 day.

12 A. That seems like a very large
13 dose.

14 Q. In any event, Doctor, I
15 suggest to you that we know that the digoxin level
16 which resulted following the administration of that
17 dose was the 2.6 nanograms level reported at 9:00 a.m.
18 Would you agree with me that if that were the level
19 resulting from that medication error that it is
20 unlikely that an excessive dose was given at that
21 time to the child?

22 A. Yes, I think it is unlikely.
23 It may have been a little - I think that Kevin
24 Pacsai weighed more than Kristin Inwood so that the
25 dose might have been larger than a usual maintenance
dose for Inwood but I don't think it resulted in a



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2 serum concentration that would be associated with
3 toxicity. If I have the times correct, I wasn't
4 aware when I did this report of this medication
5 error but if I have the times correct that you have
6 just given me I think that that is about three to
7 four hours after the error that that level was drawn.

8 Q. That is correct, Doctor.

9 A. So that I would expect that
10 that would be maybe even a little higher than the
11 steady state level after distribution took place.
12 So, I suspect the level was somewhere - this probably
13 represents the most the concentration serum would
14 have been resulting from that error.

15 Q. Thank you, Doctor. Doctor,
16 I will check the amount of the dose precisely and
17 provide that information to you.

18 A. Okay.

19 Q. Aside from Kristin Inwood,
20 Doctor, there are two other children dealt with in
21 your original reporting letter to Mr. Wiley: they
22 are John Onofre and Laura Woodcock dealt with
23 respectively at pages 11 and 12 of your first
24 reporting letter.

25 As I understand it in neither of
those cases was there in your judgment sufficient



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evidence or data available to you to allow you to
assess the involvement of digoxin intoxication, is
that correct?

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A. That is correct.

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Q. Right Doctor, there is
one additional area that I would like to discuss with
you today if I may. As I understand it, in addition
to the reporting letters which you prepared for Mr.
Wiley you were as well requested to serve as a
consultant in pharmacology to the authors of what
has been described here at the Atlanta Report, that
is, the report produced by the Centers for Disease
Control in Atlanta, is that correct?

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A. That is correct.

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A. Would you excuse me a moment
I will get my information, notes from that and I can
answer you more specifically. Some time I think
during the month of October, but it may have been as
early as September, but some time I had consented
to be a consultant for the Crown Attorney I was
consulted by Doctor - it slips my mind now - from
the CDC - Clark Heath and also by Dr. L.
Smith from the Ontario Ministry of Health asking



1
2 me if I would agree to be a consultant to the work
3 that they were doing in relation to these deaths.
4 I told them at the time that I had already agreed
5 to be a consultant to the Crown Attorney and that
6 I would like them to make sure that it was okay to
7 serve as a consultant to both groups simultaneously
8 before I would agree to do that.

9 She subsequently - they subsequently -
10 I say she because the letter I have here is from Dr.
11 Smith. I have a record that she told me late in
12 October that she had spoken to the police and the
13 Crown Attorney and that they had no objection to me
14 working simultaneously to provide consultation to
15 them, being the police and a joint consultation to
16 the Epidemiology Study Team.

17 So, following that, I did agree to
18 simultaneously serve as a consultant to both groups.
19 I did make it very clear to them that I would not
20 share, I would not myself share information provided
21 by one party with the other party in terms of
22 specific information. Obviously I was aware of
23 information from one party that may not have been
24 available to the other party and I took that
25 information into consideration when I made judgments
but I did not share specific information one with



7 1
2 the other. I told them that if they cared to share
3 information then they would do it themselves but I
4 would not share that. So, I kept the files separate
5 except if I was doing work that related to both
6 consultations I of course had all the information
7 that I had available to me out at that time.

8 Q. Doctor, what specifically
9 were you asked to do by Drs. Heath and Smith?

10 A. The general request was to
11 assist them from a pharmacological point of view in
12 their epidemiologic study of the deaths at the
13 Hospital for Sick Children. Eventually that boiled
14 down to a specific request and that was to review the
15 charts of, I believe 37 infants, and I was asked to
16 attempt to rank, or not rank, but rate each case in
17 terms of a numerical probability value, rate them as
18 to the probability that digoxin had contributed to
19 their death. I was asked to do this primarily with
20 respect to pharmacologic data but also take into
21 consideration all other data including clinical data
22 on the chart. Other consultants were looking solely
23 at clinical information.

24 Q. Doctor, at the time that this
25 request was made of you and you ultimately accepted
the assignment, had you at that point, for the



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purposes of the review requested by Mr. Wiley,
already reviewed the medical records of the some
36 children about which we are concerned?

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A. I had not reviewed the
medical records themselves at the time I consented
to consult with the CDC. I had reviewed summaries
and forensic data but I had not yet reviewed the
actual medical records at the time I agreed to
consult with the CDC.

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Q. Did you do it then on two
separate occasions; once for the purposes of the
review for the Crown Attorneys and on a second
occasion for the purposes of review for the Atlanta
group?

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A. No, my review of the actual
medical records was done on one occasion for both
purposes. Actually, what happened, was I came to
Toronto after I agreed to be a consultant for both
parties. I came to Toronto and I spent approximately
12 hours one day in a windowless room in the Hospital
with all the original records in the room with me
and all my other information from all other sources
and I sat there alone all day and looked at each
individual case, the original record as well as all
the other information I had on that case and filled



1
2 out the scoring sheets one by one with the information
3 with me at that time.

4 Q. All right. Are you saying
5 then, Doctor, that the ratings that you did for the
6 purposes of the Atlanta CDC group were done at the
7 time that you physically reviewed the medical record
8 of each child?

9 A. That is correct.

10 Q. All right. Doctor, was
11 anything provided to you in writing either by Drs.
12 Heath or Smith or any other individual connected with
13 the CDC group by way of written terms of reference
14 as to what you were being asked to do?

15 A. I would have to review all
16 my correspondence to answer that specifically but I
17 can answer it generally. At the time I did this the
18 specific terms of reference were primarily the
19 scoring sheets that I filled out. They essentially
20 incorporated the specific terms of reference.

21 Q. All right. Well, I will come
22 in a moment to the specific scoring sheets, Doctor.

23 A. Fine. At the time I did this
24 I was aware of their general approach. I was aware
25 that they were doing an epidemiologic study of the
deaths. I was not aware at the time I completed the



1
2 scoring sheets as to how they were going to use that
3 data in their study and there was no reason why I
4 should be aware of that. I didn't care to be aware
5 of it because I wanted to be as unbiased as I could.
6 So, in that sense I was blinded when I did it but I
7 was not blinded in the sense that I knew which patients
8 I was dealing with when I scored them. But I did not
9 know at the time that I filled them out how that data
10 was eventually going to be used in the entire context
11 of the whole study.

12 Q. Fine. Doctor, you have
13 mentioned some scoring sheets. Can you tell me
14 whether you designed and settled the contents of
15 the scoring sheets or were they provided to you?

16 A. I didn't design them. I
17 approved them after they were designed and said I
18 thought they were okay and then they were provided to
19 me by the CDC staff.

20 Q. All right. Doctor, who
21 determined the criteria upon which each of these cases
22 were to be rated?
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A. I think that after I had the scoring sheets then I sat down and I outlined the criteria that I thought I could use to try to separate cases into 5 categories of probability. Had I known when I designed the criteria what I knew after I filled out the sheets I might have done it differently, but that wasn't the way I wanted to do it.

What I was being asked to do actually was to assign a numerical value to an opinion of probability so that they could put numbers into the computer. Unfortunately as I got into it there were some cases that didn't fit my cubbyholes as nicely as I would have liked them to, and so I had to make a somewhat subjective decision on some cases as to which category I would eventually put them into based on my best judgment at the time I was looking at the chart. But I designed the criteria that I then used to put the numerical rating on each case.

Q. Doctor, we have heard that Dr. Alexander Nadas, chief emeritus of cardiology at the Children's Medical Center in Boston, served as a consultant cardiologist to the CDC group, if I may refer to it that way. Did you, Doctor, before rating these cases for the CDC group have the benefit of Dr. Nadas' views with respect to any of these cases



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be it orally or in writing?

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A. No, we never had any communication in any way shape or form, and I don't even know when he did his actual evaluations in the cases, we were never there at the same time, we never had any correspondence, we never talked to each other, we did our evaluations totally independently.

Q. Similarly, Doctor, we have heard Dr. Derek DeSa, Chief of Pathology at Winnipeg Children's Hospital, served as a consultant pathologist to the CDC group. Once again, prior to rating these deaths for the CDC group, and completing your work for them, had you discussed any of these cases in writing or orally with Dr. DeSa?

A. No, we never saw each other, or communicated in any way. We don't even know each other.

Q. Doctor, to be perfectly clear about the matter you outlined, what may seem many days ago but was in fact a day and a half ago, for us, the nature of the information that was available to you when you started your review for Mr. Wiley. You referred for example to summaries, case summaries prepared by Dr. Hastreiter; the toxicology data from Mr. Cimbura, to name but a few. Do I have it correctly



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that when you did these ratings for the CDC group you had available to you for your personal use all of that information that had been provided, either through the Metropolitan Toronto Police, Mr. Cimbura or the Crown Attorney's office?

A. I had everything that had been provided to me up to the date that I did the evaluations, yes.

Q. Well, can you help me, Doctor, as best you can recall, what the date was when you actually did the ratings for the CDC group?

A. I can look it up if you will give me a moment.

Q. If you would, please.

A. My records indicate that I did the on-sight review of the charts on November 19th, 1982.

Q. Would I be correct then, Doctor, in assuming that the information which was provided to you subsequent to the date of your delivery of your first reporting letter to Mr. Wiley, and we have seen several examples of that, for example the post nortem serum level in Kristin Inwood, the gutter blood study information on Janice Estrella, information of that type, was not available to you



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nor known by you at the time that you did these ratings for the CDC group?

A. That is correct.

Q. Doctor, you have told us that you personally designed the criteria by which these cases were to be rated. You have told us that the scoring sheets were provided and ultimately, were provided to you by the CDC group and ultimately approved by you.

I have provided to you what I understand to be a bound version of your completed scoring sheets of these children, together with a copy in blank of what I understand to be the scoring form provided by the CDC group; and as well a copy of what I understand to be the criteria employed by you. Do you have that volume with you?

A. Yes, I do.

Q. Mr. Commissioner, these materials have been provided to all other counsel but regrettably there was insufficient time to bind them in the same way for them, but they have been provided with the coding key in order that the identity of the involved child might be recognized. Doctor, I would ask you first if you would --

THE COMMISSIONER: They key, oh yes, all right.



K.5

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MS. CRONK: Q Doctor, I would ask you
first if you would to turn to Tab 1 of our volume.

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THE COMMISSIONER: Could we just
before we forget, we almost forgot the last one,
could we make this Exhibit 272.

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MS. CRONK: 272, sir?

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THE COMMISSIONER: Is that right?

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MS. CRONK: For the benefit of other
counsel then, sir, to make it clear, that exhibit then
includes what I will be discussing in a moment with
Dr. Kauffman, a letter dated December 14, 1982 from
Dr. Kauffman to Dr. Smith. It includes in blank a
form of scoring sheet. It includes the completed
scoring sheets on 36 of the 37 children that
Dr. Kauffman reviewed for the CDC group, the 36 being
the 36 with whom this Commission is concerned.

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--- EXHIBIT NO. 272: Letter dated December 14, 1982
from Dr. Kauffman to Dr. Smith:
Blank Form of Scoring Sheet;
Completed Scoring Sheets on
36 children.

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THE COMMISSIONER: What is the 37th?

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MS. CRONK: The 37th, sir, as I under-
stand it, was a patient by the name of Gittens who
did not die within the time frame with which we are
concerned on these wards, the child's name was Gittens.

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THE COMMISSIONER: Yes, all right.



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MS. CRONK: Q. Doctor, can I ask you first then to turn to Tab 1 of our volumes, which is the letter dated December 14, 1982 to which I have referred, which appears to be a letter from you directed to Dr. Smith of the Ontario Ministry of Health.

Doctor, I take it that this was a letter that you sent to Dr. Smith?

A. Yes, it is.

Q. And Doctor, as I read the letter, in the first two full pages you are outlining essentially a number of concerns or comments that you had as to the difficulties of interpretation that arise with various digoxin levels and concentrations in various types of specimens, including ante mortem and post mortem blood specimens; fresh and frozen tissue specimens; fixed tissue specimens; and exhumed tissue specimens; do I have that correctly?

A. That is correct.

Q. Doctor, are the comments outlined on the first two pages of this letter in substance identical to the comments that you made on the same interpretive problems in your first reporting letter to Mr. Wiley that we have earlier reviewed?

A. That is correct.

Q. Doctor, if we turn to page 3



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of your letter, if you would, please, are the criteria which you used to rate these 36 children in terms of the probability of death resulting from digoxin intoxication outlined in full on that page?

A. Yes, they are.

Q. And may I have it again for absolute clarity, Doctor, these were criterias as I understand your evidence, designed and selected by you to permit you to rate in terms of probability these deaths?

A. That is correct.

Q. And in terms of probable involvement of the drug digoxin intoxication, Doctor, I take it your highest rating was a 5?

A. That is correct.

Q. And deaths rated --

A. Pardon me, I was instructed by the CDC because of the design of the rating sheets that 5 was high and 1 was the low end.

Q. All right.

A. So that was within the design of the rating sheets, that was a given.

Q. You anticipate my questions, Doctor, because others might have approached the numerical sequence a little differently. Do I have



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it correctly then that those cases where you considered the probability of death resulting from digoxin intoxication to be most probable were rated with a 5?

A. That is correct.

Q. And conversely, those cases where you felt it least probable that death had resulted from digoxin intoxication were rated with a 1?

A. That is correct.

Q. Obviously, Doctor, there are without showing any particular brilliance at this time of the day, Doctor, three ratings within those two extremes. May we fairly infer from the ratings which you have outlined on page 3 of this letter that any death with the rating of 3 or more in your judgment was a case where there was a reasonable probability that death had resulted from digoxin intoxication?

A. There was certainly a possibility, and I suppose you could call it a reasonable probability, yes.

Q. 3 or more?

A. 3 or more. I would certainly agree that those with ratings 2 and 1 I really considered a very low probability, and I am not sure that realistically I can differentiate between 2 and 1, but I had to use up the numbers.



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Q. Thank you, Doctor. Doctor, I don't intend to review in detail with you the various criteria that you used, they are set out in full. May I with respect to Rating No. 5 draw your attention first to the rating - I am sorry, the introduction to the rating category. You have indicated that patients receiving a rating of 5 had to meet at least 4 of the following criteria?

A. That is correct.

Q. Do I take it from that doctor that it could be any 4 of the 5 outlined but it had to be 4?

A. Any 4, but 4.

Q. And Doctor, if I can draw your attention to Criteria No. 5, under Rating No. 5 you indicate:

"No digoxin prescribed at time of death."

Does that necessarily limit the patients potentially within this rating as being those for whom no digoxin was known to have been prescribed during life, or is it at the time of death?

A. I unfortunately didn't say what I meant and what I did. What I meant was no digoxin prescribed during life.



K.10

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Q. And is that what you did?

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A. That is what I did, yes.

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Q. And Doctor, with respect to

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those patients rated with a rating of 4, do I take it
that all 3 criteria outlined had to be met?

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A. That is correct.

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Q. And similarly, Doctor, with

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Rating 3, do I take it that for any patient to fall
within that category both criteria had to be met?

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A. That is correct.

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Q. And there is only 2?

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A. That is right.

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Q. And for Rating 2, Doctor, in

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that category, any patient rated with that rating had
to have at least 2 of 3 criteria which you have
outlined?

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A. Right.

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Q. But it could be any 2 of the 3?

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A. Any 2 of the 3.

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Q. And Doctor, when we move to the

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last group, the Rating 1, once again you have set out

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3 criteria. Do I have it correctly that a patient
rated with a 1 had to have at least 1 of the 3?

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A. That is correct.

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Q. But could have only 1?

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A. That is correct also.

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Q. So in some instances the

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particular patient could have satisfied all 3 criteria
but that is not necessarily the case?

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A. That is right.

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Q. Doctor, may we turn then next

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if you would to Tab 2 of our volume, which for the
benefit of other counsel is what I understand to be

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the blank scoring sheet, or at least a sample of a

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blank scoring sheet provided to you by the CDC group.

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Is that what this document represents, Doctor?

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A. Yes, it does.

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Q. And Doctor, if we can go first

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to page 1 of the scoring sheet; we see there Doctor -

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well, I am sorry, to be perfectly clear there are a

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number of questions set out on the coding sheet. The

first is:

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"Was death the result of digoxin

18

intoxication?"

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And the instructions appear, circle 1, least

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probable is assigned the number 1; most probable the

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number 5. Do I have it correctly that your probability

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rankings would thus be recorded numerically on the

right-hand side of this scoring sheet?

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A. I honestly don't recall if I

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K.12

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circled them and then a staff person wrote in in
the right-hand column, or if I wrote the numbers in
the right-hand column, I don't remember.

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Q. I put the question - you have
answered the question I posed, Doctor, but the question
was put badly, I am less concerned with the mechanics
of it than the fact that I take it if the child was
rated by you with a 2 you would simply answer the
question by circling the 2?

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A. That is correct.

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Q. And similarly if you rated a
child most probable you would indicate that simply by
circling the number 5?

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A. That is correct.

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Q. And if we move to the second
question, Doctor, it is headed:

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"This assessment is based on the
following types of data".

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The instructions are to circle 1 or more, and then
there is a resuscitation of 5 particular types of
data which potentially might be available in the
Category 6 for any other data that might be available.
On the right-hand side in writing, Doctor, we see an
indication that the codes will be: 1 equals no; or
2 equals yes, do you see that?

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K.13

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A. Yes.

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Q. Do I correctly have it, Doctor,

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then, for example, that if one of the types of data

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you were relying on were the pre mortem blood specimen

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you would insert the number 2 in the right-hand column

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indicating yes, there was that type of data that you

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had reference to?

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A. What I actually did I circled
whichever data I listed, and somebody else later did
the digital coding.

Q. All right.

A. I didn't want to get confused
by the ones and twos so I just circled them.

Q. And you circled the ones then
indicating the type of data that was in fact available?

A. That is correct.

There could be some confusion as to
how I indicated these. The fact that I may have
circled data or not circled -- well let me say it this
way: The fact that I may have not circled a particular
piece or type of data does not necessarily mean it
wasn't available. It means I didn't use it in my --
I didn't consider it in my decision.

Q. All right.

A. If I did circle it it meant it
was available and I did use it, take it into considera-
tion in my decision, and if there was something that
I considered which was not listed I simply wrote it
under "other".

Q. Do I take it then, doctor, if
you circled a particular type of information it meant
two things: First, that it existed, and secondly that



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you had relied upon it?

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A. That is right.

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And the fact that I used it had no implication as to how I used it. In other words, the fact that I circled it doesn't mean that there was abnormal data of that type; it may have been normal or abnormal data of that type.

Q. I see, doctor. And when we come to the particular cases perhaps you can provide some illustrations to us as to the kind of variability that you are discussing.

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May we turn then to the third question on page 2 of the blank coding sheet. That question is described as: "Did digoxin intoxication appear to be the result of...", and then there are five potential answers to the question.

You are instructed to circle one or more as you felt to be applicable.

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Do I have it correctly, doctor, that that question was really directed to your opinion as to the cause of digoxin intoxication where you felt that it in fact existed?

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A. When I felt that there was a reasonable probability that it existed then at that moment that I was doing this indicated my impression of



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how it could have occurred. If indeed it did.

If I felt that it was -- well, if I didn't feel that there was a likelihood of digoxin intoxication I indicated that it wasn't applicable.

If I thought that there was just no way at all that I could speculate as to the mode of administration then I circled "unable to determine".

In most cases even though it might have been highly speculative I tried to give some impression of how I thought it could have been administered. Because at the time I had no idea how this was going to be used and so I was trying to give as much information as I could or judgment kinds of data even though it might have been fairly speculative.

Q. And, doctor, the next question I think is perhaps self-explanatory. It reads: "Are there other medications which may have contributed to terminal events?"

There are various potential responses outlined. The first is a negative, the second is affirmative, "Yes"; the third is "unable to determine" and the last is "not applicable".

Do I have it correctly that if you felt that there was a medication which might have contributed to the terminal events of any particular



1
L4 2 patient you would circle the "yes"?
3 A. That is correct.
4 Q. Similarly if you felt there were
5 none you would indicate that by circling the "no"?
6 A. Either if I felt there was not
7 or I had no evidence that there were.
8 Q. All right. And in situations
9 where it was a question mark in your mind I take it
10 you would circle "unable to determine"?
11 A. That is correct.
12 Q. And then a related question,
13 doctor, is the following one: "Are there other
14 medications which may have modified response to
15 digoxin?"
16 Can you tell me first what you
17 understood that question to mean.
18 A. I primarily there was looking
19 for drug interactions that might have either changed
20 the concentrations of digoxin or the elimination of
21 digoxin or drug-drug interactions which may have
22 affected or changed the effect of digoxin on the
23 patient.
24 Q. And if you felt that there was
25 a drug that might have done that you would indicate
your answer by circling the affirmative?



Kauffman
dr.ex. (Cronk)

1

L5 2

A. That is correct.

3

Q. And similarly if you were

4

unable to determine whether or not a particular drug
or drugs had such an effect or interaction you would
indicate that you were unable to determine?

5

6

A. That is correct.

7

8

Q. And the final category on the
coding sheet, doctor, page 2, is entitled "Digoxin
Earliest Time of Fatal Dose".

9

10

There is a space for a date to be
inserted; a space for a time to be inserted, but there
is a handwritten note that appears on the bottom of
the page on the right which reads, "Note: This will
be done only for six cases. All others won't have
these lines on the form."

11

12

13

14

15

16

To the best of your understanding,
doctor, were you to complete that information in the
cases that you reviewed?

17

18

A. Frankly I don't recall putting
that information on any of them.

19

20

Q. Thank you, doctor.

21

Doctor, if we turn to page 3, that
page is largely in blank, but the heading is: "Comment
on likely route, dose, timing of administration".

22

23

Do I have it correctly that where it

24

25



L6 1
2 was possible for you to do so you would have completed
3 this page in the scoring pages to indicate what you
4 felt to be the most likely route of administration of
5 digoxin, the most likely dose that was administered and
6 the most likely timing of its administration?

7 A. That is essentially what I did.

8 What actually happened as I recall it
9 is I used this plate, this area, to make pencilled
10 informal notes, and I may have put down information
11 at times that wasn't specifically directed towards
12 these questions. But where I thought at that point in
13 time that I could, I did make comments directly re-
lated to these also.

14 Q. And, doctor, if we turn to
15 page 4, that page simply provided for any other
16 miscellaneous comments that you might have with
respect to any particular patient?

17 A. That is right. Again these
18 were informal pencil notes that I made after I filled
19 out the other things. If I felt there were other
20 things that I should note about a particular case.

21 Q. And, doctor, did the remainder
22 of the documents contained in this volume represent
23 your completed scoring cards on the 36 children with
24 whom this Commission is concerned?
25



1
L7 2 A. I haven't looked at each one
3 of them but they appear to be that, yes.

4 MS. CRONK: All right.

5 Mr. Commissioner, I note the time.
6 I would, however, make one suggestion with your
7 concurrence. It is my intention to introduce through
8 Dr. Kauffman a summary page of the results of his
9 completed scorings for these children. I think it
10 might be of benefit -- I am hoping it will be a
benefit both to you, sir, and other counsel.

11 THE COMMISSIONER: Yes.

12 MS. CRONK: With your indulgence
13 for another five minutes I believe I could do that
14 before the luncheon break. If you prefer not to I
could do it first thing after lunch.

15 THE COMMISSIONER: No, I would be
16 delighted. But where would that leave us?

17 MS. CRONK: That will leave me about
18 fifteen minutes from sitting down, sir.

19 THE COMMISSIONER: Yes. All right.
20 I think probably it would be helpful if we got the
summary now.

21 MS. CRONK: I think so too, sir.

22 Q. Dr. Kauffman, I am showing to
23 you a summary sheet entitled "Ratings by Dr. Ralph
24
25



1
2 Kauffman". I previously provided a copy of this to
3 you, doctor.

4 It is divided into two headings.
5 On the left-hand side of the page, "Re: Probablity of
6 Death as a Result of Digoxin Intoxication" and on
7 the right-hand side of the page, "Re: Cause of
8 Digoxin Intoxication".

9 Does the information set out in those
10 two columns, doctor, accurately reflect, first, the
11 particular probability ratings that you assigned to
12 these 36 children? That is the information in the
13 left-hand column. Does it accurately reflect the
14 ratings that you gave, doctor?

15 A. Yes, I believe it does.

16 Q. And, doctor, the right-hand
17 side of the page in the column entitled, "Ratings Re:
18 Cause of Digoxin Intoxication", does the information
19 set out beside each child's name in that column
20 accurately represent your answer to Question No. 3 on
21 the coding sheet? That is, your answer to the cause
22 of digoxin intoxication where you thought it was
23 reasonably probable that it existed.

24 A. Yes, I think it fairly
25 represents that.

Q. All right. And, doctor, I am



1

2

showing you now --

3

THE COMMISSIONER: That should be

4

Exhibit 273, I think.

5

--- EXHIBIT NO. 273: Document entitled, "Ratings
by Dr. Ralph Kauffman".

6

MS. CRONK: Q. Doctor, I am showing

7

to you another form of summary sheet entitled, "Summary

8

of Children Rated by Dr. Ralph Kauffman with Ratings

9

#5 to #2 Inclusive."

10

I would ask you, doctor, with

11

reference to all of those cases where you assign a

12

probability rating of 2 or greater, are those

13

children accurately identified in the first column

of this summary on the left?

14

A. I believe they are without

15

double-checking it, but I believe think they are.

16

Q. Doctor, if we move then to

17

the second column on the page, once again that

18

information I suggest and would ask for your agree-

19

ment, is a repetition of what the actual probability

20

rating was that you assigned to each of these

children?

21

A. Yes, I believe so.

22

Q. And the third column of

23

information is repetition with respect to each child

24

of what you felt to be the cause of the digoxin

25



1

2

intoxication?

3

A. I believe so.

4

5

6

7

Q. And the fourth column, doctor, I suggest contains the answer to your question in each of the ten case as to whether or not you felt other medications may have contributed to the child's terminal event?

8

A. Yes.

9

10

11

12

Q. And finally, doctor, the last column of information contains I suggest your answer to the question on the scoring sheet as to whether or not other medications may have modified the patient's response to digoxin?

13

14

A. Yes.

15

16

Q. And, doctor, I previously provided a copy of this summary to you as well to re-view?

17

A. Right.

18

19

MS. CRONK: May that be marked as the next exhibit?

20

THE COMMISSIONER: Exhibit 274.

21

22

--- EXHIBIT NO. 274: Document entitled, "Summary of Children Rated by Dr. Ralph Kauffman with Ratings #5 to #2 Inclusive".

23

24

MS. CRONK: May we take our break, sir, at this point?

25



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2

THE COMMISSIONER: All right.

3

4

We may be in trouble; we may be
sitting later tonight, I don't know, but we will see
where we stand at 4:30.

5

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MS. CRONK: Thank you, sir.

7

--- luncheon recess.

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A/BM/ak

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---Upon commencing at 2:30 p.m.

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THE COMMISSIONER: Yes, Miss Cronk.

4

MS. CRONK: Good afternoon, sir.

5

Q. Dr. Kauffman, before we broke

6

for lunch I had introduced and we had marked two

7

summary sheets. I would ask you to put Exhibit 273

8

before you which is the longer of the two. Do you

9

have that, Doctor?

10

A. Yes.

11

Q. Doctor, reviewing the probability

12

ratings which you assigned to the various children,

13

I take it that there were seven cases where you

14

assigned a rating of 3 or greater than 3 in terms of
probability.

15

A. That is correct.

16

Q. And in addition to that there

17

were three cases that you rated 2, that is, slightly
more than the least probable category?

18

A. That is correct.

19

Q. Doctor, there were 26 children

20

of our group of 36 where you felt a least probable

21

rating was appropriate?

22

A. That is correct.

23

Q. And if we look, Doctor, at

24

the seven cases where your ratings were 3 or greater

25



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and turn to what your views were concerning the cause of digoxin intoxication, with the exception of two cases amongst those seven, you felt that it was most likely to be a single overdose, an acute event. Do I have that correctly?

7

A. That is correct.

8

9

Q. Can you briefly explain for us, Doctor, what you meant by that ranking for these five children?

10

11

12

13

14

A. At that time I think I was postulating the single dose and that it had been administered as a single dose some time obviously prior to the infant's death. I don't think that these terms implied any particular time frame.

15

16

Q. In terms of the timing of the administration of the dose?

17

A. That is correct.

18

Q. All right, merely the method.

19

A. The method.

20

21

22

23

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Q. All right. Doctor, as I have said or suggested to you, there are two cases were you have indicated out of the seven cases that you were unable to determine the likely mode of administration, that is, Kristin Inwood and Jordan Hines. Do I have that correctly?



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A. That is correct.

Q. All right. Doctor, I don't intend to take you in detail through all of these cases but there are one or two that I would like to look at with you. The only child amongst the entire group of 36 to whom you assigned a most probable rating was Justin Cook, is that correct?

A. That is correct.

Q. All right. Doctor, would you turn with me to Justin Cook's coding sheet which in your book is found at Tab 37. While we are doing that, Doctor, could you put the other summary sheet in front of you if you would, please.

A. Yes.

Q. It is Exhibit 274, sir, the other summary sheet.

THE COMMISSIONER: Yes, but what else are we to look at?

MS. CRONK: The coded sheets for Justin Cook at Tab 37.

THE COMMISSIONER: Yes, yes.

MS. CRONK: Exhibit 272, sir, Tab 37.

Q. Dr. Kauffman, if we look at the second summary sheet and the information recorded there we see that of the entire group of 10 where you



1
2 had a rating of 2 or greater in terms of probability
3 only in the case of Justin Cook did you indicate that
4 another medication, I take that to mean other than
5 digoxin?

6 A. Yes.

7 Q. All right. May have contributed
8 to his terminal events. We see on your coding sheet
9 if we turn to page 2 that that is the information
10 obviously that you wrote on your coding sheet. Can
11 you explain for us, Doctor, what medication or other
12 drug was being addressed by you and why you felt it
may have contributed to his terminal events?

13 A. I think I was thinking in
14 terms of the possible role of propranolol when I
15 wrote that down.

16 Q. All right. Doctor, in
17 indicating to the CDC group that there may have
18 been a contribution by propranolol to his terminal
19 events, were you suggesting as well that propranolol
20 may have played some contributory cause directly in
the death of the child?

21 A. I was suggesting that as
22 a possibility, yes.

23 Q. All right. You will recall,
24 Doctor, from your prior discussion of the reporting
25



1
2 letters that you did for Mr. Wiley that you
3 specifically addressed the issue of propranolol and
4 its possible contribution to Justin Cook's death.
5 As I understand it, Doctor, you indicated that it
6 may well have contributed to the bradycardia and the
7 arrhythmias which the child had suffered.

8 A. That is correct.

9 Q. Was it your view, Doctor,
10 when you completed your second reporting letter to
11 Mr. Wiley, and bearing in mind what you had indicated
12 on your coding sheet for the CDC group, that it
13 was that propranolol may have directly contribu-

14 A. As I recall, I still considered
15 it a possibility that propranolol may have been a contri-
16 butory cause. I don't remember exactly if I refer
17 to that specifically in the second letter.

18 Q. Doctor, you have indicated in
19 your CDC coding sheet as well that you were unable to
20 determine whether or not any other medication may have
21 modified Justin Cook's response to digoxin. Can you
22 help us please as to what you meant by coding that
23 particular question in that way?

24 A. I didn't see any other medica-
25 tion record of any other medication being used or



1
2 administered to the child which I thought could have
3 been associated in a drug interaction which might
4 have resulted in increased digoxin concentrations
5 or modified the response to digoxin specifically.

6 Q. You did not see any other
7 medications?

8 A. There was other medication
9 but I did not see a medication which I thought would
10 specifically modify the response to digoxin.

11 Q. Why then, Doctor, ---

12 A. Well, let me rephrase that.

13 Q. I'm sorry.

14 A. I am probably confusing you.
15 I thought that propranolol could have, and I didn't
16 see any other medication that I thought that there
17 was a possibility that it would have modified the
18 response to digoxin. I was not aware of any known
19 drug interaction between digoxin and propranolol, but
20 I couldn't be absolutely certain. So, I coded the
21 modifier response question as unable to determine,
22 simply because of my uncertainty.

23 You see, I suspect that propranolol
24 in and of itself might have contributed to the
25 bradycardia but I didn't know if that was an indepen-
dent response to propranol, if indeed it did occur,



1
2 or if it was due to an interaction between propranolol
3 and digoxin. So, I could say yes, I suspected
4 propranolol may have contributed to the terminal
5 event but I could not say that this was because of
6 a modified response to digoxin.

7 Q. Doctor, if propranolol had
8 had a modifying effect in this child, can you help
9 me as to what that would mean; in other words, would
10 it render the child less susceptible to digoxin
toxicity or more susceptible.

11 A. Well, a modified response
12 could be either way.

13 Q. I see. So, the issue is an
14 unresolved one in your mind?

15 A. That is right.

16 Q. All right. Doctor, could we
17 turn then if you would please to the case of Kristin
18 Inwood. Your completed coding sheet for this child
19 appears at Tab 35. Looking at the first page of
20 your coded sheet for Kristin Inwood, Doctor, we see,
21 in terms of your probability ratings that the child
22 appears to have been originally rated at 2, that is,
23 slightly more than a least probable categorization.
Do I have that correctly?

24 A. That is right.
25



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Q. All right. And then besides that, Doctor, we see in writing a note "Dr. Kauffman called to change this 2 to a 4". Did you, Doctor, after originally rating this child, change your rating from a 2 to a 4?

7

A. Yes, I did.

8

Q. Why did you do so?

9

10

A. I did that after I was aware of the serum sample with the concentration of 491 nanograms per ml.

11

12

13

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15

16

Q. I take it then, Doctor, that you then necessarily changed the rating some time after you had completed these coding forms but after as well you had been provided with that information as to the existence of a post mortem serum sample and the level.

17

A. That is correct.

18

19

20

21

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Q. Right. Doctor, could we turn to your Comments page in your coding section. Really, the last page is an amalgamum of the last two questions on the standard coding form provided by the CDC group. We see there that you indicated that you were unable to make any comment on the likely route, dose or timing of administration. You indicated that it was not applicable. Do you see that, Doctor?



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A. Yes, that is correct.

3

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Q. And if we turn to page 2 of
your coding sheet.

5

A. Yes.

6

7

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11

Q. You indicated that you were
unable to determine the cause of digoxin intoxication.
Can you tell me, Doctor, at the time that you changed
your probability 2 rating for this child, did you
also provide the CDC group with any further revisions
to pages 2 or the Comments page of your completed
sheet?

12

13

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A. Well, no, I did not alter
those pages. I should have but I did not. I simply
told them that I thought I should change the overall
rating and I added that I was taking into considera-
tion at the bottom of page 1 post mortem blood. On
page 1, the second question, I indicated to them that
I was taking into consideration the post mortem blood,
that I was not originally aware of and they changed
the code on line number 9 to a 2 rather than a 1.

22

23

24

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Q. Doctor, I take it then that
originally ---

A. But I did not change anything
else from the original scoring sheet.

Q. Doctor, I take it then at the



1
2 time that you did your original rating you were
3 basing it on what you knew of the child's ante mortem
4 blood levels, what you knew of the concentrations of
5 digoxin found in her fixed tissues and those found
6 in her exhumed tissues but not post mortem blood
7 sample.

8 A. That is correct.

9 Q. What was there, Doctor, that
10 provided you with sufficient information once you
11 knew of the post mortem blood sample -- well, I'm
12 sorry, let me back up. Once you were informed that
13 a post mortem serum sample did exist and it had a
14 level of 491 nanograms would that have been sufficient
15 to permit you to express an opinion as to the likely
16 cause of the digoxin intoxication?

17 A. I might have been able to
18 express an opinion with a little more certainty than
19 I did originally. I can answer you to that extent.

20 Q. Have you fairly, Doctor, to
21 be fair to you, have you given that matter any thought?

22 A. No.

23 Q. Are you able to tell us?

24 A. I have not given it any thought
25 other than what I indicated in my second letter in
the police report after I had that information.



1

2

Q. To Mr. Wiley?

3

A. Right.

4

Q. Doctor, could you turn as

5

well please next to the case of Jesse Belanager.

6

Your coding sheet on this child appears at Tab 24.

7

A. Okay.

8

Q. Do you have that, Doctor?

9

A. Yes.

10

Q. Your probability rating for

11

this child, Doctor, was a 3 but we see from

12

your summary sheets that your probability rating

13

for Stephanie Lombardo was a 4. You have told us

14

in evidence over the last day and a half that in

15

reaching your conclusions concerning Jesse Belanger

16

for the purposes of the reports to Mr. Wiley you

17

were relying upon what you observed in the clinical

18

course of the child, the terminal events of the child

19

and as well the digoxin concentrations in the exhumed

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tissues of the child.

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And can you help me, doctor, as to why when it came time to rate these children to the CDC group Stephanie Lombardo received a 4 and Jesse Belanger a 3?

A. I suspect that part of the answer to that question is, as I mentioned earlier, not every case fit neatly into my preconceived descriptions, and there were times when I was not -- where I could have ranked them either way in either direction.

I think that one thing that led me -- well, a general answer is that primarily it was that I perceived a difference between the medical records and their clinical course. It is true that their digoxin data was primarily based on exhumed tissues. I can't remember if Belanger had -- yes, it was exhumed tissue, I think they both only had exhumed tissue concentrations. So the quality of the digoxin data was not tremendously different between the two.

I think the thing that swayed me with Lombardo to put her in a higher category was that she had been fairly stable for approximately five days after her surgery and then suddenly things changed. There was a clinical course that meant something catastrophic had occurred. She over a rather



BB2

1
2 short period of time developed an irregular heart
3 rate, bradycardia, a weak pulse, she vomited, she
4 had all the typical signs of digoxin intoxication,
5 much more-described in the chart much more typically
6 than there was for the other child. So that I had a
7 little more in terms of description for her death
8 event than I did for the other kids who had similar
9 digoxin data.

10 The other thing that I think
11 probably swayed me was that her serum potassium was
12 quite normal on most of the occasions from the 18th
13 to the 22nd of December, and then on the 23rd it
14 was up to 7.4 on the day of her death. Again that
15 was a piece of evidence that swayed me to make her
16 a little higher probability.

17 So I suppose the succinct answer to
18 your question would be that the description of her
19 hospital course and the contrast between her condition
20 as described during the five days post operatively to
21 the condition as described during her terminal
22 events, and the change in her potassium concentration,
23 led me to rank her with a little higher probability
24 than I did with the other baby.

25 Q. Doctor, I note with respect to
Jordan Hines the same probability rating of 5. You



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ranked him with a 3 although you ranked Lombard with
a 4. Do your comments hold true for Jordan Hines as
well?

5

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A. I think generally that is the
case, yes.

7

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Q. Doctor, still on the case of
Jesse Belanger, you will recall that you testified
yesterday and as you confirmed today, that the clinical
course of that child was an ingredient, if you will,
of the ultimate judgment which you reached quite
apart from the digoxin concentrations measured in
exhumed tissues.

13

14

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However, on my reading of your
completed coding sheet for the CDC group, no mention
is made of the clinical condition of this child, nor
of any significance that you may have attached to it.
Indeed when we turn to your comments section on
Jesse Belanger your only comment is as follows:

18

19

20

21

"The only basis for postulating
digoxin as the cause of death is
presence of digoxin in exhumed
tissues of an infant who is not
supposed to have received digoxin."

22

23

24

25

Doctor, at the time that you finished
reviewing the medical record of this child was the



BB4

1
2 clinical course considered by you to be significant?

3 A. Yes. I thought the clinical
4 course was not inconsistent with digoxin intoxication,
5 although in and of itself it certainly wouldn't
6 prove it. That together with the presence of digoxin
7 in exhumed tissues in a child who had not been pre-
8 scribed digoxin, I thought met the criteria that I
9 had described for myself to place a child in Category
3.

10 I neglected to make any notes about
11 that, or considerations on the front page of that I
12 see, and wrote only in that last comment, that is
13 probably carelessness on my part. I must say that the
14 comments that I was writing at that time were
15 informal notes that I had no idea how they were going
16 to be used, if at all, in the final -- as they were
17 incorporated into the study. I was simply noting
18 things as I completed my look at the chart, which were
19 notes to myself and presumably notes that were going to
20 be used by the CDC team as they put their report
together.

21 Q. Doctor, accepting that fully,
22 on the basis of the emphasis which you attached to
23 his clinical course in our discussions over the last
24 day and a half, and indeed in your reporting letters
25



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to Mr. Wiley, can we agree that on the face of the two, that is your completed coding report to the CDC group and your reports to Mr. Wiley, there appears to be some discrepancy on that issue?

A. Looking at them side by side I would agree with that. I suppose I should say that the CDC scoring was done a month before I drafted the so-called police report. I did it in a different context, at a different time, with a different set of thoughts and probably a different orientation.

When I did the police report a month later I made more effort, I consciously, I deliberately did not go back and compare what I had done on the CDC report because I wanted to do them independently. I suppose with all the vagaries in these cases in terms of trying to make estimates and putting down all the information I am not terribly surprised that I might have incorporated some inconsistencies between the two. I don't think it substantively changes my overall impressions on the cases.

The other thing I think that happened with the police report was that not having to place discrete numerical values on decisions I was able to -- I had the luxury of lumping a little more than I did



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with the CDC evaluation, so I may have made distinctions
in the CDC evaluation that I didn't when I drafted the
police report, I am talking about subtle distinctions.

4

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Q. Thank you, doctor.

6

Doctor, I would ask you to turn if
you would to Tab 25, the case of Janice Estrella.

7

A. Just a moment.

8

Q. Do you have that, doctor?

9

A. Yes.

10

11

12

Q. Doctor, once again looking at
your coding sheet on Janice Estrella we see the
probability rating of 5, that is most probable,
circled; is that correct?

13

A. That is correct.

14

15

Q. And beside that, doctor, we
see a handwritten note:

16

"Dr. Kauffman called to change 5 to
2."

17

18

Do you see that?

19

A. Correct.

20

21

Q. Did you in fact, doctor,
originally rate this child in terms of probability
of death caused by digoxin as a 5?

22

A. That is correct.

23

24

Q. And subsequently changed it to
2?

25



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A. That is correct.

3

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Q. What caused you to alter your
opinion in the case?

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A. As I recall the pivotal piece
of information in this child to cause me to give such
a high probability score originally was the serum
concentration of approximately 70. When I was subse-
quently informed that that was gutter blood I could
not completely ignore it, but I had to -- I couldn't
assume that it was any evidence for toxicity either.
So I felt that I had to, because of the ambiguity of
that sample, I had to assign some risk to this
patient but I didn't feel that I could put the risk
higher than 2. It was a pivotal piece of information
for me when I was making that decision.

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Q. Doctor, were the comments made
by you on the likely route, dose and timing of
administration for this child, at page 4, made before
or after you changed your probability rating?

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A. They were made before and were
never changed.

Q. They were based then I take it
in the belief that the post mortem sample was in fact
a serum sample?

A. That is correct.



1
2 Q. Doctor, I note as well -- I am
3 sorry; in the results then on Janice Estrella, I take
4 it that in the final analysis for the CDC group when
5 you rated the child you placed her as a little better
6 than a very low probability of involvement with
7 digoxin?

8 A. That is correct.

9 Q. There are two other children
10 that you placed in that category, doctor, Brian Gage
11 and Barbara Gionas, both bear a probability rating of
12 2. I am referring now to the summary sheet of your
13 results, doctor; is that correct, both of those
14 children were assigned a 2?

15 A. If I can find the right sheet.
16 Yes, that is correct.

17 Q. Neither of those children,
18 doctor, were dealt with in your reports to Mr. Wiley.
19 Indeed you will recall, I suggest, that you indicated
20 that only those cases which afforded sufficient
21 information for comment or analysis were dealt with.
22 Implicitly therefore I suggest that at that time you
23 felt there was insufficient data that allowed you to
24 deal in that way with either Brian Gage or Barbara
25 Gionas; do I have that correctly?

A. That is correct.



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Q. Why then, doctor, and on what information could you then analyze these cases when you were doing your ratings for the CDC group?

A. I'm not sure I follow your question.

Q. All right, doctor, I'm sorry, perhaps again it was put awkwardly. They were not dealt with in the police report.

A. Right.

Q. And you said in the police report that the cases not dealt with were ones where there was insufficient information available to you to permit an assessment.

A. Right.

Q. In the case of the CDC ratings however, neither of these children were put in the least probable category.

A. Right.

Q. They were nudged over that, if you will. What information was available to you that led you to be in a position to deal with Brian Gage and Barbara Gionas and to assign a probability rating of 2 for these cases?

A. Okay. Again I think these two children fell into the category of children that



1
2 didn't neatly fit either of my categories. I can
3 tell you the specific criteria if I can find my
4 notes that swayed me to put them in a 2 rather than a
5 1, if you will give me just a moment to pull the notes
6 on them. I should say while I am doing the search
7 I really viewed the rankings of 1 and 2 as being
8 children with which there was very little confidence
9 that digoxin was indeed related to their death.
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Kauffman, dr.ex.
(Cronk)

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And as I said earlier I am not sure that I really could make a real distinction between the children who received rankings of 1 or 2. It may be an artifactual distinction, but I did try to at least attempt to do it, and I would caution people not to assign a great deal of quantitative value to the difference between the 1 and 2.

Q. Well, Doctor, may I stop you there for a moment then?

In either the case of Brian Gage or Barbara Gionas bearing in mind what you have just said, was there in your view any real basis for a belief or judgment that digoxin intoxication had caused the death of either child?

A. There was some clinical evidence. For example - that I couldn't ignore - for example let me summarize Gage for you. This child was a severely cyanotic child who had a transposition with an intact septum so the blood between the lungs and the body could not mix and he was very cyanotic.

He had a balloon septostomy at 9 days. He remained cyanotic but he was fairly stable as nearly as I can tell from the chart but he was still persistently cyanotic so he had been scheduled



for future surgery.

At 0320 on the day of the scheduled surgery he suddenly developed vomiting, bradycardia, typical signs again of digoxin intoxication and I really couldn't ignore the description of those symptoms when I looked at it carefully and put him in a 1 although that was really - really his ante mortem serum concentration which I had wasn't inconsistent with his prescribed dose. So those met the criteria that I had set out for myself and technically they met the criteria that I had set out for 2 so I felt I had to put him in 2.

Now if we look at Gionas, this was a little different, but again it was an ambiguous case in terms of my self-imposed criteria.

This child came in the Hospital at one day of age with a coarctation and a hypoplastic aorta which means that he or she, I am not sure what the gender was.

THE COMMISSIONER: She.

MS. CRONK: Q. Barbara.

A. Barbara, okay. Which meant that her heart was unable to provide enough blood flow to her body, and a lot of the blood was being shunted to the lungs so she came in in severe



1
2 congestive heart failure.

3 She was operated on twice and
4 remained in failure and went progressively downhill.

5 Now the description of her course
6 leading up to her death and her death event did not
7 particular impress me as being typical of digoxin
8 intoxication, but she technically met my self-imposed
9 criteria for Category 2 because she had ante mortem
10 serum concentrations consistent with her prescribed
11 dose as the other baby, but she had ambiguous post
mortem digoxin data.

12 And those were two of the three criteria
13 I had set out so I felt I had to put her in a 2.

14 Again I say I think that either of
15 these children could have - you could argue that they
16 should be in one or the other and that is why after I
17 did this and then sat back and looked at it I really
18 wasn't sure whether there was any real difference in
19 the probability between the ones I had given a 2 to
and the ones I had given a 1 to.

20 Q. Thank you, Doctor.

21 Doctor, dealing with the category of
22 children where you did assign a probability rating of
1, as you know ---

23 THE COMMISSIONER: Before you leave
24
25



1
2 the Category 2, these are both based, are they not,
3 upon digoxin levels which were read ante mortem?

4 THE WITNESS: I think that is included
5 they both had ante mortem levels.

6 THE COMMISSIONER: Well other than
7 the fact that their deaths were presumably consistent
8 with digoxin intoxication, what you are assuming is
9 that somehow it was the therapeutic dosage, intended
10 therapeutic dosage that killed the two of them?

11 THE WITNESS: No, no, not at all.

12 THE COMMISSIONER: Then what is the
13 significance of the ante mortem readings?

14 THE WITNESS: The significance was
15 that if the ante mortem serum concentration was
16 consistent with their therapeutic dose as prescribed ---

17 THE COMMISSIONER: Yes.

18 THE WITNESS: - they could have fallen
19 into either rating 1 or 2, based solely on that
20 criteria.

21 THE COMMISSIONER: Yes, but you would
22 have presumably if there hadn't been those readings,
23 those high readings you would have put these two
24 children in 1, would you not?

25 THE WITNESS: High readings, on the
tissue?



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THE COMMISSIONER: No, no. I am
talking of the ante mortem readings. Weren't they ---

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THE WITNESS: I don't think they had
elevated ante mortem ---

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MS. CRONK: In fact, sir, to clarify
that so that the record is clear only one of those
two children had an elevated level. Brian Gage had
3.5 and Barbara Gionas' last ante mortem was a 1.9
as I recall it.

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THE COMMISSIONER: But I still don't
quite understand... Let's just look at Gionas
then.

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MS. CRONK: That is Tab 32, sir.

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THE COMMISSIONER: Yes, I have that.

I thought I had a note here that as
far as Gionas was concerned she had met your criteria
because there were ante mortem readings, but I have
got that wrong?

18

19

THE WITNESS: I believe there are
ante mortem levels on both of them.

20

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THE COMMISSIONER: Yes, but if the
ante mortem level is within the therapeutic range
how does that affect you at all?

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THE WITNESS: If it is?

THE COMMISSIONER: Yes and Gionas



1
2 apparently was.

3 THE WITNESS: Both of them - I accepted
4 both of them as being within the therapeutic range.
5 One being on the high side but I interpreted the $3\frac{1}{2}$
6 as being within an acceptable or non-toxic range also.

6
7 THE COMMISSIONER: Well, leaving aside
8 for the moment that sometimes it is a fine line between
9 1 and 2, and is one that you had difficulty drawing but
10 I still don't quite understand why either of these
11 children went into the 2.

12 THE WITNESS: Well, with respect to
13 Gage I suspect it was primarily due to the description
14 of the terminal event.

15 THE COMMISSIONER: All right. Is
16 there that much distinction between his terminal events
17 and those of many of the others? A great many of them
18 had sudden bradycardia ---

19 THE WITNESS: I think at the time I
20 was doing this it apparently impressed me that it was.
21 Maybe if I went back and looked at them side by side
22 I wouldn't feel the same today but I think that is
23 why I did what I did on that particular day.

24 THE COMMISSIONER: All right. You
25 think you put Gage in 2 because of the nature of the
terminal events; is that right?



1
2 THE WITNESS: Along with the normal,
3 what I thought was normal pre mortem serum concentration.

4 THE COMMISSIONER: Well I don't really
5 see what the pre mortem serum concentration has to do
6 with it at all if it is within the therapeutic range.

7 THE WITNESS: Only to the extent that
8 if the child had this kind of clinical course and had
9 an elevated ante mortem level it would go in a higher
category.

10 THE COMMISSIONER: Yes. All right.
11 I don't want to press it too much. I just don't see
12 the difference between Gage and Gionas on the one
13 hand and all the others that you had in number 1 and
14 almost all of them we have heard time and time again
15 that the terminal events were consistent with their
16 clinical condition and were equally consistent with
digoxin poisoning.

17 THE WITNESS: I think that there are
18 degrees of ---

19 THE COMMISSIONER: Of likelihood?

20 THE WITNESS: Of likelihood in the
21 description. In other words to me the description of
22 the terminal event of Gage is quite different from
that of Gionas.

23 THE COMMISSIONER: Yes, and you find
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it more consistent with digoxin?

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THE WITNESS: I find Gage's terminal event description more consistent than Gionas' terminal event.

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THE COMMISSIONER: All right, that might account for Gage being in 2, but it certainly doesn't account for Gionas.

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THE WITNESS: I was using two different of two of the three different criteria to put Gionas in.

10

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THE COMMISSIONER: All right. Why did you put them - if you put Gage in 2 because of that nature of the terminal events why did you put Gionas in?

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THE WITNESS: The two of the three that I was applying Gionas to was according to my notes ante mortem serum concentration consistent with prescribed doses which wouldn't allow her to be any higher than a 2 at the most.

19

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THE COMMISSIONER: You would probably put her in a 1 if there were nothing else?

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THE WITNESS: Post mortem digoxin data from exhumed tissue in her case which I couldn't ignore but they were ambiguous. They were ambiguous because they were exhumed tissue but I



1
2 couldn't ignore them.

3 THE COMMISSIONER: If I understand
4 it really the ante mortem doesn't mean anything.
5 The post mortem, it is ambiguous and it may conceivably
6 support digoxin intoxication so it would really be
7 because of the post mortem tissue readings.

8 MS. CRONK: Sir, I don't mean to
9 interrupt; there may be a misconception here.

10 You will recall that the Doctor's
11 evidence has been that he composed and designed
12 written criteria.

13 THE COMMISSIONER: That is right.

14 MS. CRONK: The criteria that he is
15 referring to are direct quotes, as I understand it,
16 Doctor, from the written criteria that he applied
17 for a rating of 2.

18 THE COMMISSIONER: Yes.

19 MS. CRONK: Such that if Gionas
20 met two of three criteria ---

21 THE COMMISSIONER: Yes. One of those
22 three then?

23 MS. CRONK: If you turn to Tab 1,
24 sir, you will find Dr. Kauffman's - please stop me
25 if I am incorrect, Doctor - you will find Dr.
Kauffman's letter to Dr. Smith and at page 3 under



1
2 your rating 2 you will see three criteria set out.

3 To fall within that grouping a
4 patient, Dr. Kauffman has told us, had to meet at
5 least two of the three.

6 Q. Dr. Kauffman, are you now
7 telling us that Barbara Gionas technically met two of
8 the three?

9 A. Yes. Can I expand on that?

10 Q. Please do.

11 A. Rating 2 they had to meet
12 two of those three criteria.

13 Now in the case of Gionas criterion
14 No. 1 is clinical condition of course not inconsistent
15 with digoxin toxicity. I thought that applied to Gage
16 but not to Gionas. "Ante mortem serum concentration
17 consistent with therapeutic digoxin dose" - I thought
18 that did apply to Gionas.

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THE COMMISSIONER: If it is consistent with a therapeutic digoxin dose I don't see why one should be suspicious at all. That would seem to be what should happen.

THE WITNESS: These were characteristics which I inserted there that would not allow it to be a 3.

THE COMMISSIONER: That is right. That brings it down from a 3 to a 2, but how does it get ---

THE WITNESS: Well, if the patient had some characteristics of 3.

THE COMMISSIONER: I see.

THE WITNESS: Now Gionas really couldn't fit into the rating, any of the 1 rating criteria. There was a record of receiving digoxin. She was receiving appropriate dose and her serum and tissue concentrations weren't - well, her serum was consistent but she had ambiguous tissue concentrations in my judgment at that point and she didn't fit criterion 3 of rating 1.

So I really couldn't legitimately put her in that category and she did technically meet two of the criteria of Category 2 and she certainly didn't fit Category 3, so that is where she fell.



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3 THE COMMISSIONER: Well now Gionas
4 I take it under rating 2 - Gionas doesn't fit any
5 of the - well, I guess there is presence in exhumed
6 or fixed tissues - no, but digoxin was prescribed
7 for her.

8 THE WITNESS: Yes.

9 THE COMMISSIONER: She couldn't possibly
10 be in rating 3 because all she satisfies is the
11 second criteria.

12 THE WITNESS: That is correct.

13 THE COMMISSIONER: She couldn't be
14 in rating 3. Now when you come to rating 2, the
15 second one of those seems to be one that would apply
16 only if she were in danger of being put in rating 3.

17 THE WITNESS: I think I agree with
18 you.

19 THE COMMISSIONER: So I wouldn't have
20 thought that would apply to her at all. I would have
21 thought that with Gionas that unless she - I suppose
22 if she satisfied condition 1 and condition 3 ---

23 THE WITNESS: But in my judgment she
24 did not satisfy condition 1.

25 THE COMMISSIONER: All right. Then
I don't think she should have been in rating 2 because
the second one doesn't really move her up from 1. It



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only takes her down from 3 which she shouldn't have
been in in the first place.

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THE COMMISSIONER: Well, I'm not
satisfied yet, but carry on.

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THE WITNESS: I will try to respond
better if I can. I share your concern because, as I
said, when I went to fit these kids into these rating
cubbyholes I had trouble fitting some of them.

6

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THE COMMISSIONER: Well, let's just
look at Gionas just for a moment to see. First of all,
you say that:

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"Her clinical condition and course
was not inconsistent with digoxin
intoxication, yes or no".

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THE WITNESS: I didn't think it was
typical of digoxin toxicity.

14

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THE COMMISSIONER: Well then, she
wouldn't have made the first one?

16

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THE WITNESS: I didn't think she made
the first cut, no.

18

19

THE COMMISSIONER: No. And the second
one:

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"The ante mortem serum concentration
was consistent with a therapeutic
digoxin dose which was prescribed."

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That was correct, she did make that?

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THE WITNESS: That's correct.

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THE COMMISSIONER: But that won't
move her from 1 to 2?

THE WITNESS: But it keeps her from
being a 3.

THE COMMISSIONER: It keeps her from
being a 3, that's right.

THE WITNESS: Among other things.

THE COMMISSIONER: And she may have
had ambiguous post mortem digoxin concentrations not
inconsistent with therapeutic doses but also not
inconsistent with digoxin toxicity.

THE WITNESS: All right.

THE COMMISSIONER: So, she did have
No. 3, Rating 2.

THE WITNESS: Right.

THE COMMISSIONER: She also had No. 2
but that doesn't really tell us anything because the
other 36 children, other 28, or whatever they were,
presumably had all the same, they had ante mortem
serum concentrations inconsistent with therapeutic
digoxin?

THE WITNESS: Well, some of them
didn't have any concentration data. Some of them had
never received digoxin and had not had any data
produced on them. So, the ones that ended up being



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l's were a composite of the three criteria under

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Rating 1.

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MS. CRONK: May I be of some assistance,
sir, if possible?

5

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THE COMMISSIONER: You can try.

7

MS. CRONK: I'll try.

(2)

8

Q Doctor, I would ask you to take
a look at Criteria 2 under Rating 1.

9

A. Yes.

10

Q Look at that criteria. It says:

11

"The patient to satisfy that

12

criteria had to have been receiving

13

appropriate digoxin dose."

14

Let's stop there. Was Gionas
receiving appropriate digoxin doses?

15

A. I thought she was, yes.

16

Q "And her serum and tissue

17

concentrations were not inconsistent

18

with the dose."

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Let's leave out the tissue for a
moment because you have said that is ambiguous, but
the serum concentration ante mortem was consistent
with the dose that she was receiving, do I have that
right?

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A. I thought it was, yes.

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Q. Yes. So, from that approach she satisfied at least one of the conditions under Rating 1 which would have placed her in that group, is that right?

A. That is right.

Q. And then if we look at Rating No. 2 there is a criteria that is quite similar but more restrictive because this time you are speaking only about serum levels and more particularly ante mortem serum levels and that is No. 2 that we have just looked at, and she satisfied that as well?

A. That is correct.

Q. So, at that point she could make it into Rating No. 1 and she is half way into making it into Rating No. 2, all right?

THE COMMISSIONER: I am sorry, because of what, No. 2?

MS. CRONK: Yes, sir.

THE COMMISSIONER: And Rating 2?

MS. CRONK: Yes, sir. In each case ---

THE COMMISSIONER: Can you tell me, what's the difference between ---

MS. CRONK: If you take a look, sir, at the criteria under Rating No. 1, Barbara Gionas.

THE COMMISSIONER: Yes.



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MS. CRONK: She was receiving, in Dr. Kauffman's view, an appropriate digoxin dose and her serum was not inconsistent, the concentration of the serum was not inconsistent with the dose.

THE COMMISSIONER: That's right.

MS. CRONK: Now, the difficulty is that the tissue concentrations he feels were ambiguous. They could or they may not have been consistent with the therapeutic dose.

THE COMMISSIONER: Yes.

MS. CRONK: Right.

Moving then to Rating 2 to see if she satisfied it.

Q. Dr. Kauffman, her ante mortem serum concentration you felt was consistent with the dose that she was prescribed, correct?

A. Yes.

Q. All right. So, she satisfied that criteria. So, she is half way into being in Rating Group No. 2, she satisfied one criteria.

THE COMMISSIONER: You have lost me when you do that.

MS. CRONK: I'm sorry.

THE COMMISSIONER: Because I don't see anything in Rating 2, No. 2 which moves her from



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Rating 1 at all.

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MS. CRONK: I am suggesting you are
entirely right, sir, that at that stage she could
almost be in either 1 or 2 by virtue of the way
Dr. Kauffman has defined his criteria.

7

THE COMMISSIONER: Yes.

8

MS. CRONK: All right.

9

10

THE COMMISSIONER: Well, it seems to
me that Rating 2 and No. 2 and Rating 1 and No. 2 are
practically the same thing.

11

THE WITNESS: I agree.

12

13

MS. CRONK: I think he said that too,
sir.

14

THE WITNESS: I agree with you.

15

THE COMMISSIONER: All right, okay.

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MS. CRONK: Q And then do we not add
one more ingredient into the picture, Dr. Kauffman,
and, that is, that this child satisfied another
criteria as you had defined them in your Rating Group 2
and, that was, you didn't know what to make of the
concentrations in her tissues?

21

A. That is correct.

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Q So, you could no longer say that
she fits solely into one because it is possible those
tissue concentrations could have been indicative of
toxicity?



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A. It could be either way. In my judgment at that time maybe I should have inserted a 1-1/2 or something but I didn't.

Q. I'm not sure, sir, I can take it much beyond that.

THE COMMISSIONER: Yes.

MS. CRONK: I may have even muddied the waters even further.

THE WITNESS: I think this illustrates the ambiguity if you will between the Ratings 1 and 2. We may be splitting hairs.

THE COMMISSIONER: Well, I think we probably are splitting hairs. If we split 2 into 1 - two hairs in one direction ---

THE WITNESS: Profused hairs.

THE COMMISSIONER: And 26 of them into another. I just don't quite get the distinction. However, we'll see. Perhaps it will dawn on me before the end of the week.

MS. CRONK: Q. Dr. Kauffman, there is one other area that I would like to cover with you and it has to do with those 26 children that you did rate with the probability rating of 1.

As you will recall, sir, an expurgated copy of the CDC group report was filed here as an



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exhibit yesterday. I don't think you need to refer to it but if you wish to please indicate so. But I can tell you that at page 13 of that report it is suggested that according to your ratings patients could have received a rating No. 1 for one of two reasons; the first reason was that limited data were available on the particular patient. The second reason was that data was available but suggested a low probability that death was due to digoxin intoxication. Is that a correct statement, Doctor, in your view of the basis upon which you placed patients into Rating Group No. 1 for one of those two reasons?

THE COMMISSIONER: Where is this, on page 13 you say?

MS. CRONK: Yes, page 13, sir.

THE COMMISSIONER: Where?

MS. CRONK: The second full paragraph of the last sentence. Would it help you, Doctor, to have it in front of you?

THE WITNESS: I think I should look at it because I think there may be the potential of a subtle meaning here which may not fit the way I was actually using my own criteria at the time, I'm not sure.



DD.9

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MS. CRONK: Q Look at page 13, Doctor,
if you would, please. Do you have it?

4

A. I have page 13.

5

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Q Second full paragraph beginning
with the words "A discussion". Do you see that, Doctor?

7

A. No.

8

Q The second full paragraph starts
with the words "A discussion".

9

10

A. Not on my page 13. Do I have
the wrong page?

11

12

Q May I see? "A discussion"
right there, the second full paragraph.

13

A. Oh, okay.

14

Q I'm referring to the last
sentence in that paragraph.

15

A. Okay.

16

Q It says:

17

"Patients may have received ... "

18

A. Okay, now I see it.

19

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Q " ... a low rating to Question
Number 1 for one of two reasons:

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limited data were available ... "
that's the first reason:

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" ... or available data suggested a
low probability that death was due to
digoxin intoxication."



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My question to you, Doctor, is that an accurate statement of the basis upon which you placed children in Rating Group No. 1, for one of those two reasons?

A. Well, it's subtlety of whether to say that I agree with the limited data, I think, because two of my criteria for Rating 1 said that no digoxin measurements were done. So, that would be limited data, could fall within that definition. The second one bothers me a little bit, I'm not sure it reflects the total or the true meaning or not and I need to think about it for a moment.

Q. Okay.

A. If you are thinking of it in terms of data suggesting a low probability, in other words, there is positive data that demonstrates a low probability, that's a little bit different than saying that there were no data to demonstrate toxicity.

Q. All right. Well, Doctor, I don't wish to cause any of us more trouble with the language than necessary. Can we try it this way.

A. Frankly, at the time I was using this I wasn't thinking of those kinds of subtleties. I thought I knew what I meant and I was doing it that way.



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Q. Doctor, were there, amongst the 26 cases that you rated with a 1 cases where there was data available which you felt in a positive way established that there was very little if any chance that those children could have died from digoxin intoxication?

A. Well, the majority of those 26 patients were fit into Criterion No. 2 which they were receiving an appropriate dose according to the chart and their serum concentrations were not inconsistent with the dose they were receiving.

Q. All right. Doctor, I take it, leaving those children aside and ones that fit into that group, there were some where you just couldn't tell because there was insufficient data available.

A. There were two who had no record of receiving digoxin and in whom no digoxin measurements had been made; there were five who were receiving an appropriate dose and no digoxin measurements were made.

Q. All right. Well, Doctor, are the ones that fell into the first group that you are describing those in which you would be prepared to say as a pharmacologist that there was a very remote possibility if any that digoxin intoxication



DD.12

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contributed to their deaths?

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A. Yes.

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Q. May I have the identity of those please, Doctor?

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A. I have a list here if you want.

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Q. All right.

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A. I can give you a handwritten list, I have nothing else, from my notes.

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Q. Thank you. Which category is that?

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A. This category here. These are the ones who were receiving digoxin and had levels which were consistent with the dose they were receiving.

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Q. All right. Doctor, you have shown me that there are 20 children of the 26 that you would place in that category.

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MR..STRATHY: I'm sorry, that category is very remote?

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MS. CRONK: Little if any possibility.

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THE WITNESS: Are you making a distinction between those and the others in Category 1 or Rating 1?

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MS. CRONK: Q. I was attempting to, Doctor. Perhaps we had better do this again. What I am effectively asking you, Doctor, is, looking at your



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group of 26 are there, amongst those cases, cases where you as a pharmacologist feel that there is only a very remote if any chance at all that death was due to digoxin intoxication? Are there any that you would thus describe?

A. Well, I thought when I was ranking these that that was the definition of Category 1, Rating 1. I think I am starting to understand what you're asking, I'm not sure.

Q. Well, let me try again.

A. These 20 - is it 19 or 20, I didn't count them?

Q. 20.

A. 20 who met, who were receiving an appropriate dose according to the record and who had a documented concentration which I thought was appropriate to that dose. There is positive data which would mitigate against toxicity. Those who had no record of receiving digoxin and in whom no digoxin measurements were done have no ---

THE COMMISSIONER: I'm sorry, I'm not too sure what you mean by "were done", were found?

THE WITNESS: Pardon?

THE COMMISSIONER: Did they attempt - you see, I can understand if they had no record of



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receiving digoxin and if they were exhumed or something and there were no digoxin traces of anything found, I can understand that child you can pretty well dismiss as having died of a digoxin overdose. I don't know if we can, but certainly it would help if there was some positive evidence on which you can base it. But what happens if they don't take any measurements at all, you don't know.

THE WITNESS: That's what I was trying to say. I think I'm starting to understand your question.

MS. CRONK: That was the point I was awkwardly trying to make, sir.

THE WITNESS: Those who met Criterion 1 and Criterion 3, based on pharmacologic data, you don't know.

MS. CRONK: Q And how many fall into those two groups? You don't have the list any more.

A. I don't have the list any more. I think it is 6.

Q And 20 fall into the other?

A. Right. I can tell you why I put that in Rating 1 and, that is, because I was asked to look at or rate these cases primarily on pharmacologic data and secondarily on clinical data. There



DD.15

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was somebody else looking at exclusively clinical,
making ratings based on primarily clinical data.

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So, when I didn't have pharmacologic
information I gave him a low probability. That was a
decision on my part at the time.

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Q. Well, Doctor, looking at your
handwritten list, amongst our group of 36 there are
then 6 children where the information simply wasn't
available to you or you couldn't tell?

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A. There were no measurements,
that's right, pre mortem or ante mortem - I mean, post
mortem.

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Q. Those were, would you kindly
confirm that for me, please, Dion Shrum, David Taylor,
and Tony Velasquez, Antonio Adamo, D'Arcy MacDonald
and the Perreault baby, amongst our group of 36?

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A. That is correct.



E/DM/ak

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Q. Am I correct, Doctor, that in the other 20 cases there was positive data available to you which would lead you, as a pharmacologist, to say that there was a very remote chance, if any, that digoxin intoxication caused the death of those children?

A. That is correct, and there was no data to the contrary.

Q. Thank you, Doctor, I think maybe we are there.

THE COMMISSIONER: Which children were they with no record of receiving digoxin I know digoxin may have been done, but I would have thought that they were the first ones that should be - which ones are they?

THE WITNESS: They are criterion 1 and 3, the middle and the right hand column of my original list.

THE COMMISSIONER: Why are they separated here then?

THE WITNESS: Because in meeting criterion 1 they had no record of ever receiving digoxin; those in criterion 3 were receiving digoxin therapeutically but no measurements were done. The only thing that differentiated those two groups were



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that one had digoxin prescribed, the other one did not.

THE COMMISSIONER: The two are Perreault and ---

THE WITNESS: I don't have the list.

THE COMMISSIONER: Would you look at the list.

MS. CRONK: I think that child, Mr. Commissioner, was not in our group of 36.

THE WITNESS: That was the child that I reviewed for the CDC, he was not a subject of this ---

THE COMMISSIONER: We don't have to worry about him.

THE WITNESS: No.

THE COMMISSIONER: The only other one is Perreault and he is the one who apparently never received ---

THE WITNESS: He was receiving digoxin therapeutically but no measurements were made.

THE COMMISSIONER: And Shrum, Taylor, Velasquez and MacDonald and Adamo ---

THE WITNESS: Were not receiving digoxin and no measurements were made.

THE COMMISSIONER: And you can't help



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me, tell me as to why?

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THE WITNESS: No.

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THE COMMISSIONER: Somebody will I

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hope some time.

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MS. CRONK: There is one other point

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that flows from that, Mr. Commissioner.

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THE COMMISSIONER: Yes.

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MS. CRONK: Q. When you say that

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they were not receiving digoxin, Doctor, are you

11

talking about that at a specific point in time,

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because the evidence before us suggests that the

13

children had received digoxin during their lives?

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A. According to my notes there was

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no record on the Hospital record that they had

16

received digoxin.

17

Q. At the Hospital for Sick

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Children?

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A. At the Hospital, yes.

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Q. Thank you, Doctor. Doctor,

one final question and then I am going to sit down

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THE COMMISSIONER: You are going to

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tell me though, Miss Cronk, that this list of Shrum,

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Taylor, Velasquez, Adamo and MacDonald all had been

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receiving digoxin and that is why they were not

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exhumed I take it.

MS. CRONK: Well, sir, maybe you
have connected the two together there too quickly.

THE COMMISSIONER: Yes, all right.

MS. CRONK: My understanding of
what the doctor has just said is that there was no
record that those children had received it at the
Hospital for Sick Children, I will have to verify
that from my own records.

THE COMMISSIONER: Were tests done
on any of these five children, Shrum, Taylor, Adamo,
Velasquez and MacDonald?

THE WITNESS: I had no record of
digoxin measurements when I did the ratings.

THE COMMISSIONER: And I take it
not in Mr. Cimbura's report, right.

MS. CRONK: Mr. Commissioner, may I
suggest, I had hoped to finish before the break, we
are now 10 minutes over the time for our break and
perhaps I can clarify this matter when we return, sir.

THE COMMISSIONER: All right. I
tell you what I want to know, I just want to know -
I can understand that you are basing any level above
1 which have to have some toxicology to make that
possible, some indication of something, if you don't



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have any indication you don't put it in one. But that wouldn't satisfy me, because if in fact the children died under circumstances that could have been digoxin toxicity, or could not have been, the fact that we don't have any information doesn't mean anything at all to me. Because if we don't have any evidence one way or the other toxicology doesn't mean anything to me at all.

THE WITNESS: That is correct. Dr. Nadas who was doing the cardiology review of these cases may very well have rated them 5, 3, or 4 when I ranked them a 1, because I was looking at the digoxin data and he was looking at the cardiology data. I looked at the clinical data secondarily, but I had to have something about digoxin there before I went beyond that.

THE COMMISSIONER: Up to even moving it up to a 1.

THE WITNESS: Because I was asked to look at it from that perspective and I think it is highly likely, although I haven't looked at the comparison, that his ratings of some of these cases were probably quite different from mine because he really wasn't considering the digoxin data primarily, he was looking at the cardiac picture of these



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children, the other side of the coin.

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Now the report, I suspect attempted
to incorporate these and put them together but that
wasn't my job at the time.

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THE COMMISSIONER: Yes, all right,
thank you. We will take 15 minutes.

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MS. CRONK: Thank you, sir.

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---Short recess.

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EE6



Kauffman
dr.ex. (Cronk)

30nov83
EE2.1
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--- upon resuming.

THE COMMISSIONER: Miss Cronk.

MS. CRONK: Thank you, Mr. Commissioner.

Q. Dr. Kauffman, I would like to clarify the matter we were discussing just before the break. Could I ask you, if you would, sir, to turn to the letter to Dr. Smith dated December 14, 1982, that is at Tab 1 of the bound volume of the material.

A. Okay.

Q. I would ask you to turn to page 3 where your criteria are set out.

A. Okay.

Q. I would ask you to look for the criteria that you have assigned for Rating No. 1.

A. Yes.

Q. Least probability.

Doctor, I am going to give you back your handwritten list that we were referring to.

Your first criterion there for that category was that the patient had no record of receiving digoxin, and no digoxin measurements done.

Stopping there for a moment, when you say no record of receiving digoxin, did you mean at The Hospital for Sick Children, or ever during the patient's life?



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A. I included any transfer notes, or notes regarding a dose prior to arriving, or in The Hospital for Sick Children's records as well as a record of any that might have been received during their hospitalization.

Q. Thank you, doctor.

A. In other words, the patient's history as well as the Hospital course.

Q. To which children, doctor, which of your 26 children, doctor, satisfied that criterion?

A. That is No. 1, I have Perreault listed.

Q. And, doctor, your second criterion under Rating No. 1 is, the patients were receiving appropriate digoxin dose and serum and tissue concentrations were not inconsistent with that dose, meaning I take it they were consistent with the doses that they were prescribed?

THE COMMISSIONER: No, should we put in "and any serum and tissue concentrations", does that mean that there were in every case serum and tissue concentrations and that they were not instances --

THE WITNESS: It should have been serum and/or.

THE COMMISSIONER: Well if there may





Kauffman
dr.ex. (Cronk)

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have been neither, there may have been neither serum
nor tissue concentrations.

THE WITNESS: That is No. 3.

THE COMMISSIONER: Yes, all right,
serum and/or tissue concentrations, there were at
least serum or tissue concentrations and those that
there were --

THE WITNESS: Yes.

THE COMMISSIONER: Okay.

MS. CRONK: Q. Let me just follow
up on that, those that were were consistent with the
appropriate digoxin dose that had been received.

THE COMMISSIONER: And there were
some.

MS. CRONK: Q. And there were some?

A. Yes.

Q. Which children, doctor, by
name, satisfy that criterion, if you would please?

A. That included Warner --

THE COMMISSIONER: They are the
ones --

THE WITNESS: They are the long list.

THE COMMISSIONER: That is the long
list?

THE WITNESS: Of the 20, yes.



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THE COMMISSIONER: All right, thank you. This list is going to be prepared, typed out.

THE WITNESS: Okay.

MS. CRONK: Q. Doctor, may we turn to the third criterion; the patients were receiving appropriate digoxindose, no digoxin measurement done, which children fulfilled that criterion?

A. That was Shrum, Taylor, Velasquez, Adamo, MacDonald.

Q. And, doctor, that is where I think I misled you. I take it then those children were receiving digoxin but you felt it to be an appropriate dose and there were no measurements available for you?

A. Correct.

THE COMMISSIONER: The only one we are concerned with is Perreault. I don't quite understand, there was no record of he ever having received digoxin, but for some reason they never examined to find out whether he had any digoxin in his tissue, is that right?

THE WITNESS: To my knowledge, I apparently didn't have any data on him when I did the review.

THE COMMISSIONER: I wonder if before



Kauffman
dr.ex. (Cronk)

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EE2.5 2 tomorrow somebody can find out why that was not done.
3 Because I can well understand not exhuming if it
4 isn't going to tell us anything, but if Perreault
5 didn't have any at any time and he did turn out to
6 have digoxin in his tissue that would put him
7 exactly in the same category as the other four.

8 MS. CRONK: Well, Mr. Commissioner,
9 before that thought progresses further. It is my
10 understanding and the evidence before you today is
11 that no digoxin was given, although originally ordered,
12 to that child while he was at The Hospital for Sick
13 Children, but that he in fact did receive some prior
14 to entering the Hospital; that is the evidence before
15 you to date, sir.

16 Q. My question to you, Dr.
17 Kauffman, I take it you were unaware that the child
18 had received some prior to entering The Hospital for
19 Sick Children?

20 A. That is correct. If indeed
21 that was the case I --

22 THE COMMISSIONER: Can I just see that
23 list again please. Then actually Perreault would
24 belong in Category 3 then would he not, or in 3, in
25 No. 3 of Rating 1, would he not? If Perreault were
receiving digoxin -- no, would he not?



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MS. CRONK: Sir, that would depend on the doctor's judgment as to whether or not the dose was appropriate. If he didn't know that a dose had been given he can't therefore at this stage I suggest make that judgment, unless it is provided to him.

THE COMMISSIONER: You say we have some record to the effect that Perreault was receiving digoxin someplace other than The Hospital for Sick Children?

MS. CRONK: That is the evidence before you, sir.

THE COMMISSIONER: Yes. All right.

MS. CRONK: Doctor, I apologize for the confusion over that, and I assume more than my share of responsibility perhaps, but I think that matter has now been clarified.

Q. One final question, doctor. After you had completed these various coding sheets on each of these children, the 36 children now I am talking about, did you have any further involvement or participation in the preparation of the CDC group report?

A. The only additional thing I did for the CDC is they asked me to write a letter to



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them giving them my criteria for the classifications. They also asked me to outline for them my ideas about their various problems of measuring digoxin in various tissues and that was represented by the letter which is enclosed which you have distributed. After that I had no participation in the report.

Q. Do I take it correctly then, doctor, that you did not play any part or have any involvement in the compilation of the report and the statistics contained in it, save for the coding sheets which you have completed and save for the preparation by you of your letter to Dr. Smith?

A. The only other thing I did I received a draft of the report to look for errors in the parts that directly pertained to what I had done. I responded to that, and that in terms of dealing with the report itself, my only participation was to check for errors representing my data as I had submitted it to them. I had no part in compiling the data or tabulating it or doing statistics on it or interpreting it.

Q. And before you saw the draft of the report for that purpose, doctor, did you have any understanding or knowledge as to the use to which the information that you had put together was intended to be put?



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A. I knew it was going to be used in some way in an epidemiological study but beyond that I had no idea how it was going to be used.

MS. CRONK: Thank you, Doctor. Thank you for your patience.

Sir, just before I do sit down, amongst the completed coded sheets that have been distributed to counsel and marked as an exhibit is one for Charlon Gardner.

The code number assigned to that child was 02062 but omitted from the package that is photocopied for counsel and for the exhibit that has been marked was a comment page by Dr. Kauffman. I would ask that that be admitted now, sir.

THE COMMISSIONER: Yes, all right.

MS. CRONK: It is being added to her page.

THE COMMISSIONER: Yes. All right. We will just put it in as page 3.

Now the interesting thing is it says page 4.

Miss Cronk, before we go any farther have we got a page 3? This says page 4.

MS. CRONK: This is an amalgam, sir, of page 3 and 4, all that there is with respect to all



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2 of these children.

3 THE COMMISSIONER: All right.

F2 4 MS. CRONK: And, Mr. Commissioner, I
5 will have the Doctor's handwritten notes with
6 respect to those categories typed up and I will
7 tender them tomorrow morning as an exhibit for
8 you, the lists that we have just been reviewing.

9 THE COMMISSIONER: Yes. I wonder if
10 we could put some kind of an asterisk with a note
11 of whatever information we have.

12 MS. CRONK: Thank you, sir, those
13 are all my questions.

14 THE COMMISSIONER: Yes. All right.

15 Mr. Hunt?

16 MR. HUNT: No questions.

17 THE COMMISSIONER: Mr. Brown?

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F-2
EMT/cr

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THE COMMISSIONER: Mr. Brown?

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MR. BROWN: I would make a submission

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at this time that Mr. Young precede me ---

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THE COMMISSIONER: I am sorry, what?

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MR. BROWN: In view of the fact that

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the report was used by the police to assist them in

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he may not be a client of the police he was retained

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by the police.

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THE COMMISSIONER: What do you say

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about that, Mr. Young?

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MR. YOUNG: I don't want to be

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difficult, Mr. Commissioner. He is not our witness

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but if Mr. Brown - at this point I would be happy

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to cross-examine the witness.

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THE COMMISSIONER: All right. Would

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you like to proceed? We will probably go on at least

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till 5 o'clock. How long do you think you will be?

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MR. HUNT: I would expect about five

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minutes.
THE COMMISSIONER: That really doesn't
get you out of today then.

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MR. BROWN: No.

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THE COMMISSIONER: All right then.

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EXAMINATION BY MR. YOUNG:

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Kauffman, ex.
(Young)

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Q. My name is David Young and I am one of the lawyers here on behalf of Metropolitan Toronto Police.

Doctor, I am going to be referring to Exhibit 116 for the short time that I am up here and you may want to have that handy. You probably do have it. That is the medical record of Justin Cook.

THE COMMISSIONER: I think you have it here somewhere.

MR. YOUNG: Perhaps Mr. Registrar can provide it.

Q. You do have it? All right.

Doctor, at page 25 of that medical record there is a note signed by Dr. Jedeikin. That note seems to indicate that Baby Cook experienced a severe cyanotic spell around 1800 hours on March 21st, 1981. Do you see that note, Doctor?

A. Yes. 21/3/1820 hours?

Q. That is correct, yes.

Actually it states that the spell seemed to be first noticed at 1800 hours.

A. Yes.

Q. And was treated later on.

Doctor, it also appears that Dr.



1
2-3 2 Jedeikin administered propranolol and that the child
3 responded well. Would you agree with that?

4 A. He describes it as almost
5 immediate. Pinking up, murmur increased.

6 Q. Right. And then, Doctor, at
7 page 29 we have a note that was signed by Nurse Nelles.
8 Nurse Nelles tells us that at 3:45 a.m. on March 21st
9 it seemed that this child began to experience some
10 difficulties. I think we could properly describe this
11 child as experiencing increasing cyanosis or a cyanotic
12 spell? Is that accurate, Doctor?

13 A. Is this the note on page 29
14 dated March 22?

15 Q. That is the one, 1981. She
16 says here:

17 "Babe settled well after 2:30 feeding.
18 Rested comfortably until about 3:45
19 when hands were - "

20 A. Noted to be.

21 Q. "...noted to be more cyanosed.
22 Vital signs were started when baby
23 began to have a seizure".

24 And then it goes on and on. Would you agree that
25 the baby appeared to be having a blue spell at that
time, 3:45.



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A. That is what appears, yes.

3

Q. That is what is indicated?

4

A. Yes.

5

Q. Doctor, about half way down

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page 27 if we could turn to that page there is an indication, a note prepared by Dr. Kantak I believe

7

that this child was administered more propranolol.

8

Initially the child was given I believe it is 0.4

9

millilitres and then a few minutes later approximately

10

3:55 the child was given another 0.2 millilitres.

11

Is that the way you read that chart,

12

Doctor?

13

A. I am having difficulty reading

14

it. I see that - I am not sure. You are talking

15

about the second note on the page 27?

16

Q. Yes, I am. Almost right in

17

the middle of the page there, Doctor.

18

A. It starts out "Called to see

19

this baby. Having blue spell".

20

Q. That is correct.

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A. Now where in that paragraph

22

are we?

23

Q. We go down to what might

24

be described as the second paragraph.

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A. Oh, now I see it. "Was given



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Inderal .4 millilitres".

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Q. Right.

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A. Okay.

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Q. Then it appears that the child did not respond in the same manner as it had at 6 o'clock. The response does not appear to have been one that the doctor was satisfied with and he gave an additional 0.2 millilitres a few minutes later.

A. Okay.

Q. Is that the way you read that, Doctor?

A. He got some atropine .1 milligrams.

Q. Right. But above that, Doctor, it refers to an additional ---

A. Oh, another .2 millilitres was pushed.

Q. Right.

A. Okay. Now I see.

Q. Then, Doctor, it does not appear that the child responded well. I think it says responded partially and my friends may be able to help me with that.

A. That is the way I read it.

Q. That is the way I read it as



1
2 well.

3 Now, Doctor, I should tell you that
4 for instance Nurse Nelles on page 29 doesn't even
5 think that the baby responded well. She says again
6 about half way down just after it says - the word
7 propanolol is underlined and it says "Another dose
8 of propanolol was administered at approximately
9 3:55".

10 Well, let's start a little earlier,
11 Doctor, I am sorry. "Propanolol was administered.
12 Babe remained markedly cyanosed" and then a little
13 further down she says "Another dose of propanolol
14 was administered at approximately 3:55. Dr.
15 Jedeikin called before this last administration of
16 propanolol babe's apex then began to dip".

17 A. Yes.

18 Q. "And was approximately 72".

19 Then there is a discussion of other
20 medication being given to the child, but, Doctor,
21 would you not agree that there did not appear to be
22 a similar good response to the administration of
23 propanolol on this occasion as there had been on the
24 earlier occasion at 1800 hours?

25 A. That is the way I understand
these notes, yes.



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Q. And, Doctor, we have heard evidence from Dr. Harry Bain. Do you know Dr. Bain?

A. I just know who he is. I don't know him personally.

Q. Dr. Bain told us and for the assistance of my friends it is at Volume 61, page 3664.

Doctor, I would be happy to read you that evidence but Dr. Bain basically told us that in light of the earlier good response - he is referring to the response at 6 o'clock in the evening - it was rather surprising that the Inderal didn't greatly assist this child later that evening at 3:45. And his general impression was that if it worked once it is likely that it is going to work again.

Would you agree that normally that is the case, Doctor?

A. Other things being equal I would agree that would be the expectation.

Q. Now, Doctor, you told us on a number of occasions that this baby was very, very likely administered a large dose of digoxin some time between - well, to be accurate before 3:30 and after 1:30 a.m. on March 21st?

A. Those were my best estimates.



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Q. Doctor, if this baby, Justin

3

Cook, was already suffering from the effects of

4

digoxin toxicity at 3:45 a.m., would that not explain

5

the very limited or lack of response of the Inderal

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that was administered at 3:45 and 3:55 a.m. just prior

7

to this child's death?

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A. I would have to think about

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that a moment.

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Q. All right.

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A. I think we have to look at

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the actions of the two drugs and think what that

13

theoretically could do and think about what kind of

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heart disease Justin Cook had.

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Justin Cook had outflow obstruction

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to his pulmonary artery, the artery going to his

17

lungs, and that was the reason for his severe

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cyanosis.

19

If I recall correctly, and correct me

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if I am wrong he had a single ventricle with an

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outflow chamber which represented a rudimentary

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right ventricle and the reason he was getting cyanotic

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periodically was that the muscle, heart muscle around

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the outflow tract of his pulmonary artery would

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contract and decrease the blood flow to his lungs

so he didn't have blood going through to the lungs



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2 so it could be oxygenated and he became cyanotic.

3 The reason for giving propranolol is
4 that it tends to relax the heart muscle or reduce
5 its contractal force. It would relax that constriction
6 and increase the flow of blood to the lungs and that is
7 apparently what - they got the response they wanted
8 and that is a common and appropriate treatment for
9 this situation.

2-9 9 Now if in fact he was having cardio-
10 dynamic effects of digoxin at the time he got that
11 3:55 dose or thereabouts, the two doses ---

12 Q. 3:45, 3:55.

13 A. 3:45, 3:55. Digoxin
14 increases the contractal force of the heart. If
15 indeed he was suffering from the effects of digoxin
16 at that point the effect of digoxin in increasing
17 the contractal force of the heart could conceivably
18 override the relaxing effect of propranolol and block
19 its effect in allowing more blood to flow to his
20 lungs. That is the best answer I can give you.

21 Q. And that might explain
22 the very limited response of the Inderal?

23 A. It could be an explanation.

24 MR. YOUNG: Thank you very much,

25 Doctor.



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THE COMMISSIONER: Mr. Brown?

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CROSS-EXAMINATION BY MR. BROWN:

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Q. Doctor, my name is Brown and
I represent Nurse Susan Nelles.

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If I might ask you a couple of
questions about a few of the babes, first of all
Baby Justin Cook.

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I believe it was your evidence
yesterday - well, actually on Monday afternoon and
also yesterday, that in your opinion an overdose of
digoxin was given to the child at some time and I
believe the most likely time frame which you posited
was between 1:30 and 3:30 in the morning. That is
approximately one to three hours before the cardiac
arrest. Am I correct in saying that that is your
best estimate?

16

A. I think that is correct.

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Q. And indeed if I recall your
testimony you were of the opinion that it would be
unlikely that the digoxin would have been administered
prior to 3:30 in the morning; is that correct?

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A. I thought that was unlikely,
yes.
Q. And if I could turn you to
the scoring sheet which you used in the Atlanta - in



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the Center for Disease Control Report and I am afraid I don't have the tab but I am sure it right towards the end.

A. I have my own copy here. I can turn to it.

MR. HUNT: Mr. Commissioner, my friend said prior to 3:30. I think he may have meant after 3:30.

THE COMMISSIONER: I thought it was between 1:30 and 3:30.

MR. BROWN: Yes, Mr. Hunt is quite correct.

Q. The question I was directing to you in your opinion it was unlikely that the digoxin would have been administered to Justin Cook after 3:30. That is less than one hour before the onset of the cardiorespiratory arrest?

A. I think I understood it the way you meant it, not the way you said it. I meant to say I thought it was unlikely that it was administered less than one hour prior to arrest.

Q. That is what I meant if I didn't say it.

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Q. If I could ask you to turn to the scoring sheet which you used for that child for the Atlanta Report study. If you could please turn to the second page of that report, or of the scoring sheet, there is a right hand margin in which certain numbers appear. At the bottom of that column appear at lines indicated as lines 22 and line 28. Do you see where those appear, Doctor?

A. Yes.

Q. My understanding is that you were asked for a limited number of cases to give an opinion as to the earliest time a fatal dose might be given. Do those numbers represent your opinion in that regard, Doctor?

A. I don't recall that they do. Those are not my handwriting, in fact, I didn't put numbers in the margin when I scored these. And I frankly don't recall putting that kind of data on any of the six sheets. I don't know if it was originally put on there and then it ended up being taken off before I did them, I really don't know.

Q. The numbers would seem to suggest that the earliest time would be on March 22nd, 2:45 in the morning, which would certainly fall within the time frame that you have described here.



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A. I may have done it but I don't have any record that I did it and I don't remember doing it. So, I can't be much more helpful to you. I don't know if they took other information that I gave in my notes and coded that or if I actually did put something down on 6/7. On the copies I was provided after the fact - you see, I did the scoring at the hospital, I left them there and after they had been coded and entered, I assume entered on the computer, I was provided copies after they had put in the coding digits. So, I don't have any record or recollection that I actually went through that exercise in those lines.

Q. So, it may well be figures put in by somebody else with all the information.

A. Could well have been, I just don't know.

Q. Very well. If I could then turn to Baby Janice Estrella.

THE COMMISSIONER: Could it not be based upon what you did say? Obviously your comment "Was likely administered within one hour of the onset of terminal symptoms" and the onset was 3:45. So, they may have put in ---

THE WITNESS: They may have



GG3
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2 interpreted my comments and coded it in that way,
3 yes.

4 THE COMMISSIONER: It's sort of a
5 bad interpretation.

6 THE WITNESS: No, I don't disagree
7 with it, I just don't recall doing it.

8 MR. BROWN: Q. So, it is certainly
9 within your time frame.

10 A. Yes.

11 Q. If I recall your examination
12 yesterday, the one hour time that you said would be
13 a minimum, you fixed in relation to the time of
drawing the sample which was 4:30.

14 A. Yes.

15 Q. So, the latest time which you
16 posited would be 3:30 a.m.; the earliest time which
17 you posited would be approximately 1:30 a.m. and
this figure would fall somewhere in the middle.

18 A. Yes.

19 Q. So, it is not inconsistent
20 with the time window that you presented to us in your
21 evidence?

22 A. No.

23 Q. If I might turn then, Doctor,
24 to Baby Janice Estrella. We have heard that in your
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original report to Mr. Wiley, the report dated in December of 1982, you were of the opinion at that time that in view of the post mortem readings of 70 and 74 nanograms per milligram in the serum you considered those readings to be excessively high and, coupled with the low tissue reading, you considered those readings would be consistent with a large dose of digoxin administered shortly prior to death.

I would refer you to page 7 of your letter and in the second full paragraph, last half of the paragraph I believe deals with that initial opinion which you have.

A. Yes. I have it here.

Q. My recitation I believe of your evidence was correct, at that time you were of the opinion that a significant dose of digoxin had been given to that child shortly before her death?

A. That is correct.

Q. And then you were subsequently advised of the source of that sample, that the source of that sample was taken from the pelvic cavity of the child and I understand you were also advised of the results of a gutter blood study that had been conducted by the Hospital for Sick Children and Mr. Cimbura, the Centre of Forensic Sciences,



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is that correct?

A. That is correct.

Q. And on the basis of that new information I believe you changed your opinion and the evidence which you gave yesterday, and this can be found at Volume 71, page 5729, was that in view of the new information - well, I can simply read it to you.

A. Do I get a chance to look back at my previous days of testimony?

THE COMMISSIONER: Yes, yes, you do. I think Mr. Young is going to come to your assistance.

THE WITNESS: Thank you.

MR. YOUNG: You're welcome.

THE WITNESS: Which page are you on?

MR. BROWN: 5728.

THE COMMISSIONER: I guess you can read it just in case people don't have it.

MR. BROWN: Q. I will be starting at line 7, Doctor, the question starts there:

"Q. And we know, Doctor, as you learned, that the Estrella level of 72 nanograms on the post mortem specimen was obtained from a gutter blood or pelvic cavity specimen. In light of



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"your knowledge of this case, Doctor,
and the results of the gutter blood
study which was provided to you, would
you, as a pharmacologist, dismiss the
72 nanograms level as meaningless in
light of the source and the manner of
its sampling?"

And your response is on page 5729:

"A. I wouldn't dismiss it, but
I have to have much less confidence in
it. The problem this poses is that
this was the one piece of information
that really made the difference in
making that judgment in this case
and losing confidence in that number
in this particular case really left
very little else to deal with."

And I believe on the basis of that
information you were given you wrote a second report
to Mr. Wiley. The letter was dated January 17, 1983.
If I might refer you to the second page of that
letter, the last paragraph:

"The estimate of possible doses of
digoxin outlined in paragraph 4 under
'Summary and Evaluation of Janice



GG7 1
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3 "'Estrella' is only valid if one assumes
4 that the level of 70 nanograms per
5 millilitre measured in 'gutter blood'
6 reflects the actual post mortem serum
7 concentration of digoxin. Since the
8 measurement of digoxin in the post
9 mortem blood was critical to making a
10 judgment in the Estrella Case, it is
11 my opinion that this case is open to
12 serious challenge and in itself does
13 not provide a strong basis for a theory
14 of homicide."

15 And it is my understanding, Doctor,
16 that that is your opinion today, is that correct?

17 A. That is correct regarding that
18 specific case.

19 Q. Regarding simply the case of
20 Janice Estrella.

21 A. Right.

22 Q. Indeed, I suggest, Doctor,
23 that it was on the basis of that new information
24 on the significance of the post mortem sample that
25 you changed the scoring of Janice Estrella in the
Atlanta Report. If you wish to refer to the scoring
sheet of Janice Estrella, which is at Tab 25. On



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the front page of that scoring sheet there is a notation that "Dr. Kauffman called the change 5 to 2" and I believe Miss Cronk asked you this before you originally scored the child as a 5, but am I correct in saying that in view of the new information on the post mortem blood you changed it to a 2?

A. That is correct.

Q. If, Doctor, the post mortem levels of 70 and 74 which were obtained from the pelvic cavity are valid samples and accurately represent the amount of digoxin in the post mortem blood of Baby Janice Estrella, I believe that on that basis you attempted to calculate the dose, the time and the mode of administration for that child, and if I could refer you to page 7 of the first letter that you wrote to Mr. Wiley, the second to last paragraph on that page, the last two sentences, I believe you first stated that:

"It is unlikely that the dose was administered orally since this infant was quite ill and was receiving oral fluids by nasogastric tube."

I take it, Doctor, that that is also the opinion which you presently hold?

A. Yes, I agree with that.



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Q. And the next sentence:

"It is also somewhat unlikely that the dose was diluted in the bottle of intravenous fluid or buretrol since the acute onset of critical symptoms and the relatively low myocardial levels are not particularly consistent with a prolonged infusion."

And I would take it, Doctor, that that is also your present opinion today?

A. I still agree with that.

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Kauffman
cr.ex. (Brown)

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Q. And the reason, Doctor, that you would rule out the intravenous bag or buretrol as a potential mode of information I suggest is two-fold: first of all, the acute onset of the critical symptoms demonstrated by this child on the morning of her death.

A. That was part of it.

Q. That was part of it. I take it the critical symptoms in this child started approximately at 2:40 a.m. in the morning, and if I might refer you back to the paragraph at the top of page 7, the last sentence:

"At 2:40 on 11/1/81 she was noted to be gasping..."

Were those the terminal events that you were referring to as being acute?

A. I'm sorry, I lost you. She is where?

Q. I'm sorry?

A. Oh, at 2:40 on 11/1 she was noted to be gasping?

Q. "...with rapidly increasing respiratory rate."

A. Yes. I think that that is what I was identifying as her terminal event.



Kauffman
cr.ex. (Brown)

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Q. So that in your opinion, or the basis of your opinion was that the acute critical symptoms or the acute onset of critical symptoms commenced somewhere around 2:40 that morning?

A. In that neighbourhood, as near as I could tell from the chart.

Q. And the second reason that you suggested or came to the opinion that the administration by the IV bag or buretrol was unlikely was the relatively low myocardial levels found in this child, is that correct?

A. Yes, although they were fixed tissues but they were still quite low even for fixed tissues I thought.

Q. Doctor, if a dose of digoxin was placed in the buretrol of an intravenous line and then allowed to infuse into the line within a period of, let us say, 30 minutes, when would you expect the onset of the critical symptoms to occur?

A. Well, that depends on a number of variables and this gets into a complex area that I don't think I have discussed before. I can't give you a simple answer. It depends, one, on the volume in the buretrol into which the dose was placed, whether it was 5 cc. or 100 cc. or somewhere in between because



GG2.3

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2 that defines the amount of fluid into which it
3 diffuses and has to run in before it is all into the
4 patient; it depends on the length of the IV tubing
5 at that point in time because that's the dead space
6 through which it has to go; it depends on whether the
7 IV tubing was hanging below the crib at some point
8 so that the drug, because of a difference of specific
9 gravity might layer out in the depended part of the
10 tubing; it depends on the intravenous flow rate
11 because that determines the length of time it takes
12 the first part of the drug to arrive at the patient
13 and it also determines the length of time it takes
14 for the entire dose to be infused into the patient.

15 There are data that I don't have with
16 me which have worked out these kinds of fluid
17 dynamics. So, there are variables here that can make
18 an enormous difference; in other words, if the dose
19 was placed in the buretrol in a relatively large
20 volume, I'm talking something a little more than 40
21 millilitres, and the IV flow rate was 3 to 10 milli-
22 litres per hour, which wouldn't be improbable for
23 this kind of a patient, I don't know what it was
24 actually, it might take 6 to 8 hours for 100 per cent
25 of that dose to actually be infused into the patient.

The first bit of digoxin would



Kauffman
cr.ex. (Brown)

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reach the patient in, if the dead space in the tubing was 15 to 18 millilitres, which isn't unusual, depending on the length of the extension tubing, the first digoxin would reach her at a flow rate of 10 in something over 1 to 2 hours and then dribble in over the following hours.

Q. Well if I could perhaps put a couple of hypotheticals to you. If you could assume that the digoxin was diluted in no more than 10 cc. of the IV fluid and if you would assume that that amount of material was infused into the child over a period of no more than 30 to 40 minutes, and let us assume that the IV line runs relatively straight to the child and there is not much of a dip, on that basis would you be able to give an opinion as to when you would expect to see the onset of the critical symptoms in that child?



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A. You mean the entire 10 millilitres would go without any other fluid being added to the buretrol at all, would be allowed to infuse into the patient?

Q. Yes.

A. That is very hypothetical because that would allow air into the line behind the fluid and that usually is done, but I will deal with that.

THE COMMISSIONER: Before you deal with it though are these facts upon which we have had evidence?

MR. BROWN: No, there has been no evidence on these facts.

THE COMMISSIONER: Are you just - you don't need to answer this, but are you picking these facts out of the air or do you have some knowledge of them? Because --

MR. BROWN: They are of some relevance.

THE COMMISSIONER: They certainly have relevance if they happen to be true, but do you know whether they are or not, does it assist us?

MR. BROWN: I think the facts I am putting to him are reasonable and may well come out at some later time.



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THE COMMISSIONER: I see, all right.

THE WITNESS: I can't tell you exactly but I will do the best I can, can you give me dead space for the tubing and flow rate?

MS. BROWN: Q I am asking you to assume that the quantity that was in the buretrol was infused at an even rate over a period of 30 to 40 minutes, what that comes down to in terms of cc's per minute, it is obviously greater than 10 cc's, perhaps between 15 and 20 cc's per hour.

A. Okay. I suspect that once that dose was in during that time that you could see critical symptoms, possibly see critical symptoms I would guess anywhere from 15, 20, 30 minutes up to maybe an hour or more. It is extremely variable when you read the literature about the onset of symptoms from known intoxication, the onset is somewhat variable.

Q. You would expect nonetheless to see the onset of critical symptoms within a - within a relatively short period of time?

A. A relatively short time once the dose was all in.

Q. If I may then turn, Doctor, to Baby Kevin Pacsai. I believe it was your evidence



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this morning, although in this respect I am only relying on my notes, that you had difficulty in determining whether this child received a dose of digoxin orally or parenterally. But if I may, if I could put it this high it was probably your better view that he received an oral dose of digoxin, would that be a fair summary?

A. I think that is as I recall a fair summary of what I said.

Q. And if I also recall you said if he received an oral dose it would be most likely that that dose was administered in a very broad time frame between six to twelve hours before the onset of the critical conditions, is that a correct summary of what you said?

A. A rather broad time frame, yes, long enough for distribution but I doubt if it was before 12 hours because we have normal potassium, and he looked okay prior to that, the twelve hours beforehand.

THE COMMISSIONER: It was greater than twelve hours?

THE WITNESS: Greater than twelve hours, I doubt if it was greater than twelve hours.

MR. OLAH: Just briefly, is that twelve



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hours before death or onset of symptoms?

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MR. BROWN: Well, I am just coming

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to that, Mr. Commissioner.

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THE COMMISSIONER: Yes, all right.

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MR. BROWN: Q If I recall, in response

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to a similar question that Miss Cronk posed to you

8

this morning, you stated that the benchmark that you

9

were using was the onset of critical symptoms which

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occurred somewhere in the neighbourhood of 3:30 or

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3:45 on the morning of this child's death, is that

12

correct?

A. That is when I got a clue from
the chart that something had changed, yes.

13

Q. So, applying the time window

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that you posited to that benchmark, would I be fair in

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saying that it is your opinion that the oral dose of

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digoxin could have been administered as early as 3 or 4

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p.m. on the previous afternoon, March 11th, that is

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12 hours before 3:30, the morning of March 12th?

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A. I think I postulated that it

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could have possibly been given on the schedule dosing

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time of 2100, or could have been given at both

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scheduled times, the time before that and at 2100.

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THE COMMISSIONER: I thought we

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decided there wasn't --

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THE WITNESS: That is where I was
confused.

THE COMMISSIONER: You said there
wasn't one at 9 o'clock.

THE WITNESS: When I wrote my report
I was under the impression that he had received two
doses, and today looking at their medication sheet I
notice that it looked like it may have been only one
dose. I think that that dose could be included in
the outside limits, that is that time.

MR. BROWN: Q. The first dose that
you thought he had been given?

A. Was 2100.

Q. The 2100 on the evening of
March the 11th, which would be approximately six hours
prior to the onset of the critical symptoms at about
3:30, 3:45 the following morning?

A. Right.

Q. So that dose could be included?

A. It could be.

Q. And from what you were saying,
one could also include, could you not, the period of
time six hours prior to the administration of that
dose, that is approximately 3, 3:30 in the afternoon
up until 9 o'clock in the evening, would that be
correct?



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A. I would have to - I think it is unlikely, although he could have, I think it is unlikely that he received as much before that potassium level of 3.9 was drawn and I can't remember the exact time of that, before I answer you specifically as to time frame.

MR. OLAH: I think that was 1745 in the afternoon.

THE WITNESS: That would have been 5:45 in real time.

Q. So it would be unlikely in your opinion that the dose was administered orally prior to 5:30 the previous afternoon.

A. Yes, I think, yes, I think that's fair.

Q. But that some time between 5:30 that afternoon and the onset of the critical events at 3:30 the following morning, would be a period of time in which oral administration could be possible to achieve those levels?

A. I think I agree that those are the outside limits of the range that I could postulate. I felt from looking at the chart that things really started changing at 3:35 point when the baby was described as being very different. Reading other



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cases reported in the literature with mainly
intoxication, those kinds of time frames after an
oral dose have been described in that ball park.



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Q. If I might refer you to page 8 of your letter to Mr. Wiley, the first letter. You also entertained the possibility, and I am reading the last sentence of the last full paragraph, that this child could have received an overdose of digoxin through the intravenous route some three to six hours prior to the onset of the critical symptoms, that is another opinion that you hold, is that not right?

A. That was another guestimate, and I thought it was a reasonable possibility. I really couldn't say whether or not it was intravenously or oral, but I thought it was a little more probable orally but I wouldn't argue one way or the other.

Q. Two sentences above that on the same page of the report, or three sentences it starts:

"The excessive dose could have been given either orally or parenterally. For example, an excessive dose could have been given orally at the scheduled dosing time of 2100 hours 11/3/81 and result in the clinical course which ensued."

And I believe this morning Miss Cronk took you through an exercise and we determined that



1
2 the prescribed dose at that time was .02 milligrams
3 of digoxin; do you recall that figure?

4 A. Was it .02 or .0-- .02 you are
5 correct, you are correct.

6 Q. And I believe you calculated
7 that that quantity translated into a volume of .4
8 millilitres of the digoxin elixir.

9 A. Yes, I agree.

10 Q. And Miss Cronk then took you
11 through the exercise which you performed on the bottom
12 of page 8 and the top of page 9 of your report in
13 attempting to calculate a minimum oral dose of digoxin
14 to produce the concentrations found in the serum and
15 the tissues, and as a result of that exercise you
16 posited a minimum oral dose of .7 milligrams of the
17 digoxin, that is the accurate figure?

18 A. Yes.

19 Q. Which would be contained in
20 14 millilitres of the digoxin elixir?

21 A. Correct.

22 Q. And the minimum dose which
23 you postulated would exceed the prescribed dose by
24 approximately 35 times, is that correct?

25 A. I think that is correct.

Q. Therefore, the dose would be



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2 significantly larger in volume. I believe you said
3 that it might well require a different container or
4 syringe to be administered than with the prescribed
5 dose, is that correct?

6 A. That is correct.

7 Q. Doctor, are you familiar with
8 the procedures used at the Hospital for Sick Children
9 to administer digoxin to children?

10 A. No, I am not.

11 Q. Well, if I could perhaps put
12 to you 4 assumptions which we have to test at some
13 later time. If you would assume with me that in
14 order to give a dose of digoxin, a nurse first
15 consults a medication card which is kept for each
16 child, and upon that card is written the dose and
17 the time of administration for that child.

18 If you would then assume as the second
19 feature, that having read that card the nurse would
20 then take the drug and draw up the appropriate amount
21 of digoxin.

22 The third step that the nurse who
23 drew up the medication would then take that syringe
24 to another nurse along with the medication card,
25 show the card and the syringe to the other nurse and
ask her to confirm that the quantity that is drawn



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2 up in fact reflects the quantity prescribed.

3 If you would assume for me that those
4 are the steps involved at the Hospital for Sick
5 Children to administer digoxin to children, would
6 you agree with me that if a dose which exceeds the
7 prescribed dose by 35 times was shown to the nurse
8 who was to check the dose that that huge increase
9 in volume would be apparent to the second nurse.

10 A. I think it would be.

11 Q. And indeed, if because of
12 that large volume a different container or syringe
13 had to be used in order to administer that volume,
14 the second nurse that checked the syringe would
15 probably notice that there was in fact a different
16 vehicle being used, would you agree with me that that
17 would be likely?

18 A. I certainly would.

19 Q. And if you assume with me,
20 Doctor, that that in fact was the procedure used
21 when the dose prescribed to be administered at
22 9 o'clock on the evening of March the 11th to Kevin
23 Pacsai, and those four steps were used, would that
24 not in your mind decrease the likelihood that the
25 dose administered at that time exceed the prescribed
dose by 35 times?



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2 A. I think the only way that could
3 happen would be if the procedures were grossly violated.

4 Q. And if the procedures were not
5 grossly violated, but in fact were conformed with,
6 that would reduce, in your opinion would it not,
7 the likelihood of an excessive dose being administered
8 at that time?

9 A. Yes, I think so.

10 MR. BROWN: Thank you, Doctor.

11 THE COMMISSIONER: I think we will
12 just take a poll. Mr. Strathy, how long do you think
13 you are going to be?

14 MR. STRATHY: Probably an hour and
15 a half to two hours, Mr. Commissioner.

16 THE COMMISSIONER: Miss Thomson?

17 MS. THOMSON: Mr. Scott will be
18 conducting the cross-examination and I think he will
19 be about an hour to an hour and a half.

20 THE COMMISSIONER: An hour to an
21 hour and a half?

22 MS. THOMSON: Yes, sir.

23 THE COMMISSIONER: Mr. Ortved.

24 MR. ORTVED: I think about half an
25 hour, Mr. Chairman.

THE COMMISSIONER: Miss Symes?



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MS. SYMES: Depending upon the
questions asked by Mr. Strathy and Mr. Scott I would
say an hour and a half.

MS. JACKMAN: Depending on the
questions that go before I would say half an hour to
an hour.

THE COMMISSIONER: Yes, Mr. Olah.



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MR. OLAH: I would be probably about half an hour, Mr. Commissioner, but have difficulty on Friday. I would not be most likely able to attend on Friday and I would be most grateful, sir, if you could accommodate me by --

THE COMMISSIONER: Well perhaps you could arrange with someone. I don't know why I should pick on her but Miss Symes would let you in ahead of her. Up the queue somewhere.

I was just thinking because this looks like tomorrow before we get to the parents. Are any of the parents intending to be longer than an hour? I would like to get through everybody except the parents tomorrow and of course if we reach the parents we might get on to them as well.

Are any of the parents in trouble on Friday?

MR. TOBIAS: Yes, Mr. Commissioner, I will be required to be in another court Friday morning but I could probably be here by 11:30 at the latest.

THE COMMISSIONER: Well that looks to me as though that would be all right but you might also see perhaps if you may want to take over from somebody as well tomorrow.



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Well, I think I would like to start --

I know it is against the principles but I would like to start early tomorrow. It is the only real chance we have and I would like to sit until we are through everybody but the parents if we can tomorrow and I think ensure that Dr. Kauffman can first of all leave on Friday afternoon and secondly if he does come back to Toronto it will be for other purposes than ours. So 9:30, does it shock anybody?

Well I think we will make it 9:30 then tomorrow morning and you will be here, Mr. Strathy, that is the main thing, and is it all right with you, Dr. Kauffman, early morning?

THE WITNESS: I usually start my day much earlier than that.

THE COMMISSIONER: We have found that doctors do start earlier and quit earlier.

THE WITNESS: I would be most grateful if I could eventually use my return ticket to Detroit.

THE COMMISSIONER: What time is that on Friday?

MS. CRONK: It is being negotiated, sir.

THE COMMISSIONER: Well let's start at 9:30 tomorrow and see how we are making out by noon. --- whereupon the hearing was adjourned at 4:45 p.m. until Thursday, the 1st day of December 1983 at 9:30 a.m.

